

Supplementary table 1. Pain scale, type of pain, gestational age and blinding characteristics in all included studies (n=354)

\* = Non-appropriate use of the scale.

Trial	Scale	Type of pain	Age of the infant		Blinding characteristics (see notes below the table)
			Preterm	Term	
Abbasoglu 2015a [1]	NIPS	Procedure, heelstick	X		⊕
Abbasoglu 2015b [2]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Abdallah 2013 [3]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Acikgoz 2015 [4]	N-PASS	Procedure, endotracheal suctioning	X		Unclear
Ahuja 2000 [5]	Not defined	Procedure, intramuscular injection*	X*	X*	Unclear
Akcam 2004a [7]	DAN	Procedure, heelstick		X	⊕⊕
Akcam 2004b [6]	DAN	Procedure, heelstick		X	⊕⊕⊕⊕
Akcan 2009 [9]	PIPP/PIPP-R	Procedure, invasive procedure	X		⊕
Akcan 2016 [8]	NIPS	Procedure, heelstick		X	⊕
Akman 2002 [10]	NFCS	Procedure, heelstick		X	⊕
Alemdar 2017 [12]	NIPS	Procedure, venipuncture	X		No blinding
Alemdar 2018 [11]	PIPP	Procedure, intravenous cannulation	X		No blinding
Alencar 2012 [13]	CRIES NFCS	Postoperative pain* Postoperative pain	X X	X X	⊕⊕
Alinejad-Naeini 2014 [14]	PIPP/PIPP-R	Procedure, endotracheal suctioning	X		No blinding
Altun-Koroglu 2010 [15]	NFCS	Procedure, heelstick		X	⊕⊕⊕⊕
Anand 1999 [16]	PIPP/PIPP-R	Procedure, endotracheal suctioning	X		⊕⊕⊕⊕
Anand 2008 [17]	PIPP/PIPP-R	Procedure, endotracheal suctioning	X		⊕⊕⊕⊕
Ancora 2013 [18]	EDIN PIPP/PIPP-R	Ongoing pain, ventilator treatment Ongoing pain, ventilator treatment*	X X		⊕⊕⊕⊕
Anell-Olofsson 2015 [19]	EDIN	Postoperative pain	X		⊕⊕⊕
Angeles 2015 [20]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕
Asmerom 2013 [21]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Aversa 2012 [22]	CRIES	Procedure, heelstick*	X		Unclear
Avino 2014 [23]	DAN	Procedure, intubation	X	X	No blinding
Axelin 2006 [25]	NIPS	Procedure, endotracheal/pharyngeal suctioning	X		Unclear
Axelin 2009 [24]	PIPP/PIPP-R	Procedure, endotracheal/pharyngeal suctioning and heelstick	X		⊕⊕⊕⊕
	NIPS	Procedure, endotracheal/pharyngeal suctioning and heelstick	X		
Azarmnejad 2015 [26]	NIPS	Procedure, arterial blood sampling		X	Unclear

Badiee 2009 [30]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕
Badiee 2013a [27]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Badiee 2013b [31]	PIPP/PIPP-R	Procedure, intubation	X		⊕⊕
Badiee 2014a [28]	PIPP/PIPP-R	Procedure, heelstick	X		No blinding
Badiee 2014b [29]	PIPP/PIPP-R	Procedure, urethral catheterization, suprapubic aspiration	X		⊕
Baharlooei 2017 [32]	NIPS	Procedure, heelstick	X		⊕
Ballantyne 2003 [33]	PIPP/PIPP-R	Procedure, PICC insertion	X	X	⊕⊕⊕⊕
Baudesson 2017 [34]	PIPP/PIPP-R DAN	Procedure, venipuncture Procedure, venipuncture	X X		⊕⊕⊕⊕
Bauer 2004 [35]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕⊕
Beheshtipoor 2017 [36]	PIPP/PIPP-R	Procedure, venipuncture	X		⊕
Beken 2014 [37]	NIPS	Procedure, venipuncture		X	⊕⊕⊕⊕
Bellieni 2001 [40]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕⊕
Bellieni 2002 [39]	DAN	Procedure, heelstick		X	⊕⊕⊕
Bellieni 2007 [41]	ABC	Procedure, heelstick		X	No blinding
Bellieni 2013 [38]	DAN	Procedure, Intramuscular injection		X	No blinding
Bembich 2013 [43]	NIPS	Procedure, heelstick		X	⊕
Bembich 2018 [42]	NIPS	Procedure, heelstick		X	⊕
Benini 1993 [44]	NFCS	Procedure, circumcision		X	⊕
Bergomi 2014 [45]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Bernardini 2011 [46]	PIPP/PIPP-R	Procedure, heelstick	X		No blinding
Bilgen 2001 [47]	IBCS	Procedure, heelstick		X	Unclear
Bilgen 2013 [48]	NIPS	Postoperative, circumcision*		X	⊕
Biran 2011 [49]	DAN PIPP/PIPP-R	Procedure, venipuncture Procedure, venipuncture	X X		⊕⊕⊕⊕
Bo 2000 [50]	NIPS	Procedure, heelstick	X	X	Unclear
Bouwmeester 2001 [51]	COMFORT VAS	Postoperative pain Postoperative pain*		X X*	⊕⊕⊕⊕
Bouwmeester 2003a [52]	COMFORT VAS	Postoperative pain Postoperative pain*	X X*	X X*	No blinding
Bouwmeester 2003b [53]	COMFORT VAS	Postoperative pain Postoperative pain*		X X*	⊕⊕⊕
Boyle 2006 [54]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕#
Britto 2017 [55]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕
Bueno 2011 [56]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕⊕⊕

Bueno 2012 [57]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Butler-O'Hara 1998 [58]	NIPS	Procedure, circumcision	X	X	⊕
Çağlar 2019 [59]	NIPS	Procedure, PICC insertion	X		No blinding
Çağlar 2017 [60]	NIPS	Procedure, intramuscular injection		X	No blinding
Caltagirone 2018 [61]	NFCS	Procedure, lumbar puncture		X	⊕⊕⊕⊕
Campbell-Yeo 2012 [62]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Campo 2014 [63]	NIPS	Procedure, heelstick		X	⊕
Carbajal 1999 [64]	DAN	Procedure, venipuncture		X	⊕⊕⊕⊕
Carbajal 2002 [65]	DAN	Procedure, subcutaneous injection	X		⊕
Carbajal 2003 [67]	DAN	Procedure, venipuncture		X	⊕⊕⊕⊕
Carbajal 2005 [66]	DAN PIPP/PIPP-R	Procedure, heelstick Procedure, heelstick	X X		⊕⊕⊕⊕
Cardoso 2014 [69]	PIPP/PIPP-R	Procedure, arterial puncture	X		⊕
Cardoso 2017 [68]	PIPP/PIPP-R	Procedural, endotracheal suctioning	X	X	Unclear
Castral 2008 [70]	NFCS	Procedure, heelstick	X		No blinding
Ceelie 2013 [71]	NRS COMFORT-B	Postoperative pain* Postoperative pain		X* X	⊕⊕⊕⊕
Chandra 2018 [72]	PIPP/PIPP-R	Procedure, laser treatment	X		Unclear
Chen 2017 [73]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕⊕⊕
Chermont 2009 [74]	NFCS NIPS PIPP-R	Procedure, intramuscular injection Procedure, intramuscular injection Procedure, intramuscular injection		X X X	⊕⊕**
Chiabi 2016 [75]	NIPS	Procedure, heelstick		X	Unclear
Chidambaram 2014 [76]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Chik 2017 [77]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕⊕
Chiroco 2017 [78]	PIPP/PIPP-R	Procedure, heelstick	X		No blinding
Choudhary 2016 [79]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Chuang 2018 [81]	PIPP/PIPP-R	Procedure, ROP-examination	X		No blinding
Chrysostomou 2014 [80]	N-PASS	Ongoing pain, ventilator treatment	X	X	Unclear
Cignacco 2008 [82]	Bernese pain scale for infants PIPP/PIPP-R VAS	Procedural, endotracheal suctioning Procedural, endotracheal suctioning Procedural, endotracheal suctioning*	X X X*		⊕⊕⊕⊕
Cignacco 2012 [83]	Bernese pain scale for infants	Procedure, heelstick	X		⊕
Codipietro 2008 [84]	PIPP/PIPP-R	Procedure, heelstick		X	No blinding
Cogen 2011 [85]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕

Collados-Gomez 2017 [86]	PIPP/PIPP-R	Procedure, venipuncture	X		⊕
Cong 2011 [87]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Cook 2017 [88]	PIPP/PIPP-R	Procedure, perifer intravenous catheter insertion	X	X	⊕⊕⊕⊕
Costa 2013 [89]	NIPS	Procedure, ROP-examination	X		⊕⊕
Curtis 2008 [90]	FLACC	Procedure, venipuncture		X	⊕⊕⊕⊕
De Bernardo 2019 [91]	NIPS	Procedure, venipuncture		X	⊕⊕
de Sousa Freire 2008 [92]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Dekker 2019 [93]	COMFORT-neo	Procedure, intubation (MIST)*	X		⊕
Desai 2017 [94]	PIPP/PIPP-R	Procedural, endotracheal suctioning	X		No blinding
Dezhdar 2016 [95]	PIPP/PIPP-R	Procedure, venipuncture	X		⊕
Dhaliwal 2010 [96]	PIPP/PIPP-R	Procedure, ROP-examination	X		No blinding
Dilen 2010 [97]	Leuven Pain scale	Procedure, venipuncture*	X*	X*	⊕⊕⊕⊕
Dilli 2014 [98]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Dur 2018 [99]	NIPS	Procedure, heelstick		X	⊕
Ecevit 2011 [101]	NIPS	Procedure, heelstick	X		No blinding
Efe 2007 [102]	NIPS	Procedure, venipuncture		X	No blinding
Efendi 2018 [103]	PIPP/PIPP-R	Procedure, “invasive procedure”	X		Unclear
Elserafy 2009 [104]	PIPP/PIPP-R	Procedure, venipuncture	X		⊕⊕⊕⊕
Eriksson 1999 [106]	PIPP/PIPP-R	Procedure, heelstick or venipuncture		X	⊕
Eriksson 2004 [105]	PIPP/PIPP-R	Procedure, heelstick		X	⊕
Erkul 2017 [107]	NIPS	Procedure, intramuscular injection		X	No blinding
Erkut 2017 [108]	NIPS	Procedure, heelstick		X	Unclear
e Silva 2008 [100]	COMFORT-neo NIPS	Ongoing pain, ventilator treatment Ongoing pain, ventilator treatment*	X X		⊕⊕⊕⊕
Fallah 2016 [109]	NIPS	Procedure, lumbar puncture	X	X	⊕⊕⊕⊕
Fallah 2017 [110]	NIPS	Procedure, intramuscular injection		X	No blinding
Ferber 2008 [111]	Recording sheet adopted from NIDCAP	Procedure, “blood test stick”*	X*		⊕⊕
Fernandez 2003 [112]	Brazelton neonatal behavior assessment scale	Procedure, heelstick*		X*	⊕
Gabriel 2013 [113]	NIPS	Procedure, heelstick		X	Unclear
Gajbhiye 2018 [114]	PIPP/PIPP-R	Procedure, intramuscular injection		X	No blinding
Gal 2005 [115]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Galderisi 2018 [116]	PIPP/PIPP-R	Procedure, insertion of continuous glucose monitoring vs heelstick	X		⊕

Ganesh 2008 [117]	CRIES	Postoperative pain		X	⊕⊕⊕⊕
Gao 2018 [118]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Garry 2006 [119]	NIPS NRS	Procedure, circumcision Procedure, circumcision *		X X*	⊕
Gaspardo 2008 [120]	NFCS	Procedure, various procedures	X		⊕⊕⊕⊕
Ghaffari 2014 [121]	PIPP/PIPP-R	Procedure, suprapubic aspiration vs transurethral catheterization	X	X	⊕
Gharehbaghi 2007 [122]	CRIES	Procedure, venipuncture*	X	X	⊕
Gibbins 2002 [124]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕⊕⊕⊕
Gibbins 2003 [123]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕***
Gitto 2012a [125]	NIPS PIPP/PIPP-R	Procedure, intubation - NIPS Ongoing pain, ventilator treatment – PIPP*	X X		Unclear
Gitto 2012b [126]	CRIES	Procedure, heelstick*	X		No blinding
Grabska 2005 [127]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Gradin 2002 [128]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕⊕
Gradin 2004 [129]	VAS	Procedure, venipuncture*	X*		⊕
Gradin 2005 [130]	PIPP/PIPP-R	Procedure, heelstick		X	⊕
Grunau 2004 [131]	NFCS	Procedure, heelstick	X		⊕
Guinsburg 1998 [132]	NFCS	Ongoing pain, ventilator treatment*	X		⊕
Gunay 2018 [133]	NIPS	Procedural, bath	X	X	Unclear
Hadian 2013 [134]	PIPP/PIPP-R	Procedural, endotracheal suctioning	X		No blinding
Harrison 2003 [135]	NFCS (subset of NFCS)	Procedure, heelstick	X	X	⊕
Hartley 2018 [136]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Hashemi 2016 [137]	NFCS	Procedure, intramuscular injection		X	⊕
Hatami Bavarsad 2018 [138]	DAN	Procedure, intramuscular injection		X	⊕
Ho 2016 [139]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Holliday 1999 [140]	“Behavioral scale”	Procedure, circumcision*	X*		Unclear
Holsti 2006 [141]	NFCS	Procedure, heelstick	X		⊕
Holsti 2011 [142]	BIIP	Procedure, heelstick	X	X	⊕
Howard 1994 [144]	Postoperative comfort score	Procedure, circumcision Postoperative		X*	⊕⊕⊕⊕
Howard 1999 [143]	Brazelton behavioral state	Procedure, circumcision*		X*	⊕⊕⊕⊕
Hsieh 2017 [145]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Hsieh 2018 [146]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear

Huang 2004 [147]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Hui-Chen 2013 [148]	N-PASS	Procedure, venipuncture	X		Unclear
Hwang 2015 [149]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Im 2008 [150]	NIPS	Procedure, heelstick		X	No blinding
Ivars 2012 [151]	VAS	Procedure, nasopharyngeal suctioning*	X*		⊕
Jain 2000 [152]	NFCS (validated adaptation)	Procedure, venipuncture*	X*	X*	⊕⊕⊕⊕
Jain 2001 [153]	NFCS (validated adaptation)	Procedure, heelstick*	X*	X*	⊕⊕⊕⊕
Jain 2006 [154]	NIPS	Procedure, heelstick	X	X	⊕⊕
Jebreili 2015 [155]	PIPP/PIPP-R	Procedure, venipuncture	X		⊕
Johnston 1999 [162]	PIPP/PIPP-R NFCS	Procedure, heelstick Procedure, heelstick	X X		⊕⊕⊕⊕
Johnston 2003 [163]	PIPP/PIPP-R NFCS	Procedure, heelstick Procedure, heelstick	X X		⊕
Johnston 2007 [161]	PIPP/PIPP-R NFCS	Procedure, heelstick Procedure, heelstick	X X		⊕
Johnston 2008 [160]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Johnston 2009 [159]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Johnston 2011 [158]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Johnston 2012 [156]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Johnston 2013 [157]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕
Joyce 2001 [164]	RIPS (Riley Infant Pain scale)	Procedure, circumcision*		X*	⊕
Kabatas 2016 [165]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Kahraman 2018 [166]	NIPS & COMFORT-neo	Procedure, heelstick Procedure, heelstick	X X		Unclear
Karaca 2016 [167]	NIPS	Procedure, intramuscular injection		X	⊕
Kashaninia 2008 [168]	NIPS	Procedure, intramuscular injection		X	No blinding
Kass 2001 [169]	MBPS (modified behavioral pain scale)	Procedure, circumcision*	Unclear	Unclear	Unclear
Kaur 2003 [171]	NFCS	Procedure, lumbar puncture		X	⊕⊕
Kaur 2019 [172]	PIPP/PIPP-R	Procedure, venipuncture	X	X	Unclear
Kataria 2015 [170]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕
Khan 2017 [173]	N-PASS	Ongoing pain, Jet device vs Bubble device (CPAP)	X		Only the statistician
Kleberg 2008 [174]	PIPP/PIPP-R	Procedure, ROP-examination	X		No blinding

Klingenberg 2014 [175]	EDIN	Ongoing pain, highflow nasal cannulae vs nasal CPAP	X		No blinding
Klotz 2017 [176]	EDIN	Ongoing, nHFOV vs nCPAP	X		No blinding
Kozer 2006 [177]	DAN VAS	Procedure, suprapubic aspiration or transurethral catheterization Procedure, suprapubic aspiration or transurethral catheterization*		0-2 months* X*	⊕
Kristoffersen 2011 [179]	PIPP/PIPP-R	Procedure, N.G tube insertion	X		⊕
Kristoffersen 2018 [178]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕
Kucuk 2017 [180]	PIPP/PIPP-R	Procedure, heelstick	X		No blinding
Kucuk 2018 [186]	PIPP/PIPP-R	Procedure, endotracheal suctioning	X		No blinding
Kucukoglu 2015 [182]	NIPS	Procedure, intramuscular injection		X	⊕
Kucukoglu 2016 [181]	PIPP/PIPP-R	Procedure, intramuscular injection	X		No blinding
Kumari 2017 [183]	PIPP/PIPP-R	Procedure, heelstick	X		⊕⊕⊕⊕
Kurdahi 2017 [184]	N-PASS	Procedure, heelstick	X		⊕
Kvist 2002 [185]	PIPP/PIPP-R	Procedure, heelstick or venipuncture		X	No blinding
Lago 1998 [187]	Behavioral sedation score	Ongoing, ventilator treatment*	X*		⊕
Lago 2008 [188]	NIPS PIPP/PIPP-R	Ongoing pain, ventilator treatment* Ongoing pain, ventilator treatment*	X X		⊕
Larsson 1998a [190]	NFCS	Procedure, heelstick or venipuncture		X	⊕
Larsson 1998b [189]	NFCS	Procedure, venipuncture		X	⊕
Leelanukrom 2012 [191]	NIPS	Postoperative*	Unclear	Unclear	⊕
Lehr 2015 [192]	NIPS	Procedure, heelstick		X	⊕⊕⊕⊕
Leite 2009 [193]	NFCS	Procedure, heelstick		X	⊕
Lemyre 2006 [195]	PIPP/PIPP-R	Procedure, PICC insertion	X		⊕⊕⊕⊕
Lemyre 2007 [194]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕⊕⊕⊕
Leng 2016 [196]	NFCS	Procedure, heelstick		X	⊕⊕⊕⊕
Liaw 2010 [199]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Liaw 2011 [197]	NFCS	Procedure, intramuscular injection		X	⊕
Liaw 2012 [198]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Lima 2013 [201]	NIPS	Procedure, venipuncture	X	X	Unclear
Lima 2017 [200]	NIPS	Procedure, intramuscular injection		X	Unclear
Ling 2005 [202]	NIPS	Procedure, venipuncture		X	⊕⊕⊕⊕
Liu 2010 [203]	NIPS	Procedure, venipuncture	X	X	⊕
Liyanage 2014 [204]	PIPP/PIPP-R	Procedure, venipuncture		X	No blinding

Long 2003 [205]	NFCS	Procedure, venipuncture	X	X	⊕
Lopez 2015 [206]	PIPP/PIPP-R	Procedure, venipuncture	X		Unclear
Lynn 2000 [207]	MIPS	Postoperative pain*		X*	Unclear
Mahmud 2017 [208]	MBPS (modified behavioral pain scale)	Procedure, 5 different procedures *		X*	Unclear
Malakian 2017 [209]	CRIES	Procedure, heelstick*		X	⊕
Mandel 2012 [210]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕
Manjunatha 2009 [211]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Marcatto 2011 [212]	NIPS	Procedure, PICC insertion	X		⊕
Marchette 1989 [213]	Izard's Maximally Discriminative Facial Movement System	Procedure, circumcision*	Unclear	Unclear	⊕
Marel 2007 [214]	COMFORT VAS	Postoperative pain Postoperative pain*		X X	⊕⊕⊕⊕
Marsh 2005 [215]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Matar 2016 [216]	NPAS	Procedure, venipuncture or nasopharyngeal suctioning*	X*	X*	No blinding
Mathai 2006 [217]	DAN	Procedure, heelstick		X	Unclear
Mathai 2011 [218]	NIPS	Procedure, heelstick		X	⊕
McCullough 2008 [219]	NFCS	Procedure, nasogastric tube insertion	X		⊕⊕⊕⊕
McGinnis 2016 [220]	N-PASS	Procedure, heelstick		X	No blinding
Mehta 2010 [221]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕⊕⊕
Mekkaoui 2012 [222]	DAN	Procedure, venipuncture	X	X	⊕
Milazzo 2011 [223]	NIPS	Procedure, arterial puncture	X		⊕
Milbrandt 2018 [224]	NIPS	Procedure, clubfoot manipulation and casting	Unclear	Unclear	⊕⊕⊕⊕
Mir 2018 [225]	NIPS	Procedure, heelstick		X	No blinding
Mitchell 2004 [226]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕
Mitchell 2013 [228]	PIPP/PIPP-R	Procedure, tracheal or nasal suctioning	X		No blinding
Mitchell 2016 [227]	PIPP/PIPP-R	Procedure, heelstick		X	⊕
Modarres 2013 [229]	DAN	Procedure, intramuscular injection		X	⊕
Moore 2001 [230]	Not defined	Procedure, intravenous cannulation*	X*	X*	⊕⊕
Morrow 2010 [231]	NIPS	Procedure, heelstick		X	No blinding
Mosayebi 2014 [232]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Murmu 2017 [233]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Nanavati 2013 [234]	PIPP/PIPP-R	Procedure, removal of adhesive tape	X		No blinding
Nesargi 2015 [235]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕⊕



Nimbalkar 2013a [237]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Nimbalkar 2013b [236]	PIPP/PIPP-R	Procedure, N.G tube insertion	X	X	⊕
Noori Shadkam 2008 [238]	NIPS	Procedure, venipuncture		X	Unclear
Norman 2005 [241]	PIPP/PIPP-R	Procedure, Freestyle vs HemoCue technique	X	X	No blinding
Norman 2008 [239]	PIPP/PIPP-R	Procedure, heelstick or venipuncture		X	Unclear
Norman 2011 [240]	EDIN/ALPS-0 PIPP	Procedure, intubation Procedure, intubation	X		⊕⊕⊕⊕
O'Sullivan 2010 [242]	N-PASS	Procedure, ROP-examination	X		⊕⊕
Obedin 2015 [243]	CHEOPS	Ongoing pain, NEC*	X*		Unclear
Obeidat 2015 [244]	PIPP/PIPP-R	Procedure, heelstick		X	⊕
Ogawa 2005 [245]	NFCS	Procedure, heelstick or venipuncture		X	⊕⊕⊕⊕
Okan 2007 [246]	NFCS	Procedure, heelstick	X		⊕⊕⊕⊕
Olischar 2014 [247]	PAT	Postoperative	X	X	⊕⊕⊕⊕
Olsson 2011 [249]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕
Olsson 2016 [248]	PIPP/PIPP-R	Procedure, venipuncture	X		No blinding
Olsson 2018 [250]	ALPS-Neo VAS	Procedure, hip examination* Procedure, hip examination*		X X*	⊕⊕⊕⊕
Osinaike 2007 [251]	NIPS	Procedure, venipuncture		X	⊕
Ou-yang 2013 [252]	N-PASS	Procedure, heelstick	X		⊕⊕⊕⊕
Overgaard 1999 [253]	NIPS	Procedure, heelstick		X	⊕⊕⊕⊕
Ozdogan 2010 [254]	NFCS	Procedure, heelstick		X	⊕
Pandey 2013 [255]	PIPP/PIPP-R	Procedure, N.G tube insertion	X		⊕⊕
Pandita 2018 [256]	NIPS	Procedure, intramuscular injection	X	X	⊕
Patel 2003 [257]	PIPP/PIPP-R NIPS	Procedure, heelstick Procedure, heelstick	X X		⊕⊕⊕⊕
Peng 2018 [258]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Penido 2011 [259]	NIPS Comfort	Procedure, intubation Procedure, intubation*	X X		⊕⊕
Pereira e Silva 2007 [260]	NIPS Comfort	Procedure, intubation Procedure, intubation*	X X		⊕⊕
Perrone 2017 [261]	ABC	Procedure, heelstick		X	⊕
Perroteau 2018 [262]	PIPP/PIPP-R DAN	Procedure, heelstick Procedure, heelstick	X X		⊕
Peyrovi 2014 [263]	NIPS	Procedure, heelstick		X	No blinding
Qiu 2017 [264]	PIPP/PIPP-R	Procedure "daily painful procedures"	X		⊕

Qiu 2018 [265]	PIPP/PIPP-R	Ongoing, ventilator treatment*	X		⊕
Ramenghi 1996a [268]	Not defined	Procedure, heelstick*	X*		⊕
Ramenghi 1996b [267]	Not defined	Procedure, heelstick*		X*	⊕
Ramenghi 1999 [266]	Not defined	Procedure, heelstick*	X*		Unclear
Ravikiran 2011 [269]	NIPS VAS	Procedure, intramuscular injection Procedure, intramuscular injection*		X X*	⊕
Ravishankar 2014 [270]	PIPP/PIPP-R	Procedure, N.G tube insertion	X	X	⊕⊕⊕⊕
Rawal 2018 [271]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕⊕
Razaghi 2015 [272]	DAN	Procedure, venipuncture		X	Unclear
Rioualen 2018 [273]	NFCS	Procedure, venipuncture		X	⊕
Rodrigues 2017 [274]	PIPP/PIPP-R	Procedure, pharyngeal/naso-pharyngeal suctioning	X		⊕
Rogers 2006 [275]	DAN	Procedure, bladder catheterization	Unclear		⊕⊕⊕⊕
Romantsik 2014 [276]	NFCS BIIP	Procedure, toe-lance Procedure, toe-lance		X	⊕
Roofthoof 2017 [277]	PIPP/PIPP-R COMFORT-neo	Procedure, PICC insertion Procedure, PICC insertion	X X		Unclear
Rosali 2015 [278]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕
Rossi 2018 [279]	NIPS	Procedure, Guthrie test and/or intramuscular injection		X	Unclear
Rouzrokh 2010 [280]	NIPS	Postoperative pain	Unclear		Unclear
Rushforth 1995 [281]	Not defined	Procedure, heelstick*	X*	X*	⊕⊕⊕⊕
Saarenmaa 1996 [282]	CHEOPS NIPS	Procedure, endotracheal suctioning* Procedure, endotracheal suctioning	Unclear	Unclear	⊕
Saarenmaa 1999 [283]	CHEOPS NIPS	Ongoing, ventilator treatment* Ongoing, ventilator treatment*	X* X*		⊕⊕⊕⊕
Saarenmaa 2001 [284]	CHEOPS NIPS	Procedure, endotracheal suctioning* Procedure, endotracheal suctioning	X* X		⊕⊕⊕⊕
Sabety 2013 [285]	DAN	Procedure, venipuncture		X	⊕
Saeedi 2010 [286]	NIPS	Procedure, intramuscular injection	Unclear		Unclear
Saeedi 2011 [287]	NIPS	Procedure, intramuscular injection		X	⊕
Sahoo 2013 [288]	PIPP/PIPP-R	Procedure, venipuncture	X	X	⊕
Sajedi 2006 [289]	NIPS	Procedure, intramuscular injection		X	⊕⊕
Saththasivam 2009 [290]	NFCS	Procedure, heelstick or venipuncture		X	⊕
Sato 2007 [291]	NFCS NIPS	Procedure, Freestyle vs lancet device	X	X	⊕
Scaramuzzo 2013 [292]	ABC	Procedure, heelstick		X	Unclear

Şener Taplak 2017 [293]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕
Seo 2016 [294]	PIPP/PIPP-R	Procedure, heelstick		X	Unclear
Shah 1997 [298]	NIPS	Procedure, venipuncture or heelstick		X	No blinding
Shah 1998 [297]	Not defined	Procedure, heelstick*		X*	⊕
Shah 2003 [296]	Not defined	Procedure, heelstick*		X*	⊕
Shah 2008 [299]	Not defined VAS	Procedure, intramuscular injection* Procedure, intramuscular injection*		X* X*	⊕⊕⊕⊕
Shah 2017 [295]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Shao-Hui 2014 [300]	NIPS	Procedure, heelstick	X	X	Unclear
Sharara-Chami 2017 [301]	NIPS	Procedure, circumcision		X	⊕
Shavit 2017 [302]	NFCS VAS	Procedure, frenotomy Procedure, frenotomy*		X X*	⊕⊕⊕⊕
Shen 2015 [303]	N-PASS	Procedure, heelstick	X	X	No blinding
Shin 2014 [304]	PIPP/PIPP-R	Procedure, PICC insertion	X		⊕⊕⊕⊕
Shrestha 2012 [305]	NIPS	Procedure, heelstick or venipuncture		X	Unclear
Shukla 2018a [306]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕
Shukla 2018b [307]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Simons 2003 [308]	NIPS PIPP/PIPP-R	Procedural, endotracheal suctioning Procedural, endotracheal suctioning	X X		⊕⊕⊕⊕
Simonse 2012 [309]	PIPP/PIPP-R	Procedure, heelstick	X		No blinding
Sinkey 2015 [310]	CRIS	Procedure, circumcision*		X	Unclear
Slater 2010 [311]	PIPP/PIPP-R	Procedure, heelstick		X	⊕⊕⊕⊕
Soltani 2018 [312]	NIPS	Procedure, heelstick		X	⊕⊕
Sorrentino 2017 [313]	NIPS	Procedure, heelstick		X	No blinding
South 2005 [314]	PIPP/PIPP-R	Procedure, circumcision		X	⊕⊕
Stang 1997 [315]	Behavioral distress scale	Procedure, circumcision*		X*	⊕⊕
Stevens 1999 [316]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Stevens 2005 [317]	PIPP/PIPP-R	Procedure, heelstick	X		Unclear
Stevens 2018 [318]	PIPP/PIPP-R	Procedure, heelstick	X	X	⊕⊕
Suhrabi 2014 [319]	NIPS	Procedure, intramuscular injection		X	Unclear
Sujatha 2017 [320]	NIPS	Procedure, intramuscular injection		X	⊕
Sujatha 2018 [321]	NIPS	Procedure, intramuscular injection		X	⊕
Sundaram 2013 [322]	PIPP/PIPP-R	Procedure, heelstick	X		⊕
Taddio 1997 [327]	NFCS	Procedure, circumcision		X	⊕⊕⊕⊕
Taddio 2000 [323]	NFCS	Procedure, circumcision		X	Unclear

Taddio 2008 [324]	PIPP/PIPP-R	Procedure, heelstick, venipuncture and intramuscular injection		X	⊕⊕⊕⊕
Taddio 2009 [325]	PIPP/PIPP-R VAS	Procedure, venipuncture and intramuscular injection Procedure, venipuncture and intramuscular injection*		X X*	⊕⊕⊕⊕
Taddio 2011 [326]	Not defined	Procedure, venipuncture*		X*	⊕⊕⊕⊕
Taeusch 2002 [328]	Not defined	Procedure, circumcision*		X*	No blinding
Tekgündüz 2019 [329]	NIPS	Procedure, pharyngeal/naso-pharyngeal suctioning	X		⊕
Tekin 2016 [330]	N-PASS	Procedure, intramuscular injection		X	⊕⊕
Thakkar 2016 [331]	PIPP/PIPP-R	Procedure, heelstick		X	⊕⊕⊕⊕
Tinner 2013 [332]	EDIN Bernese pain scale for newborns	Ongoing, pain after vacuum extraction and Procedure, heelstick		X X	Unclear
Trevisanuto 2005 [333]	NIPS	Ongoing, two different CPAP-systems*	X		No blinding
Ullsten 2017 [334]	PIPP/PIPP-R BIIP	Procedure, venipuncture Procedure, venipuncture	X X	X X	⊕
Upadhyay 2004 [335]	NFCS	Procedure, venipuncture		X	⊕
Uyan 2005 [336]	NFCS	Procedure, heelstick		X	⊕
Uzelli 2015 [337]	NIPS	Procedure, intramuscular injection	X		No blinding
Valeri 2018 [338]	NFCS	Procedure, venipuncture	X	X	⊕
van Dijk 2002 [339]	COMFORT VAS	Postoperative pain Postoperative pain*		X X*	⊕⊕⊕⊕
van Lingen 2001 [340]	Facies scale	Ongoing, pain after vacuum extraction*		X*	⊕⊕⊕
Vaughn 1996 [341]	Infant pain scale scoring system	Postoperative pain*		X*	⊕⊕⊕⊕
Vezyroglou 2015 [342]	PIPP/PIPP-R	Procedure, pharyngeal/naso-pharyngeal suctioning	X		⊕⊕⊕⊕
Ward-Larson 2004 [343]	PIPP/PIPP-R	Procedure, endotracheal suctioning	X		Unclear
Weatherstone 1993 [344]	Newborn pain behavior scale	Procedure, circumcision*		X	⊕
Wester 1993 [345]	VAS	Procedure, heelstick*	Unclear	Unclear	⊕⊕⊕⊕
Yilmaz 2011 [346]	NIPS	Procedure, heelstick		X	Unclear
Yu 2017 [347]	NIPS	Procedure, heelstick		X	No blinding
Zahed Pasha 2017 [348]	NIPS	Procedure, intramuscular injection		X	⊕⊕⊕⊕

Zargham-Boroujeni 2017 [349]	NIPS	Procedure, venipuncture	X	X	⊕
Zeerati 2015 [350]	Parts of PIPP/PIPP-R	Procedure, ROP-examination*	X		⊕
Zeraati 2017 [351]	PIPP/PIPP-R	Procedure, ROP-examination	X		⊕
Zhu 2015 [352]	NIPS	Procedure, heelstick		X	No blinding

### Legend:

- ⊕ = Blinding for those performing the pain assessment
- ⊕⊕ = Blinding for those performing the painful procedure and those performing the pain assessment
- ⊕⊕⊕ = Blinding for those administering the pain-relieving intervention and those performing the pain assessment
- ⊕⊕⊕⊕ = Blinding for those administering the pain-relieving intervention, those performing the painful procedure and those performing the pain assessment
- # = Blinded to sucrose/water but not pacifier
- ## = Blinded for dextrose/water but not for skin-to-skin contact
- ### = Blinding for sucrose and NNS and water and NNS, but not for the sucrose alone group

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Supplementary table 2. Trials that used more than one scale. For full citations, see supplementary table 1.

	Scale 1	Scale 2	Scale 3	Comparison
Alencar 2012	NFCS	CRIES		Not compared
Anand 1999	PIPP/PIPP-R	COMFORT-neo		Not compared
Ancora 2013	EDIN	PIPP/PIPP-R		Not compared
Axelin 2009	PIPP/PIPP-R	NIPS		“NIPS scores correlated with PIPP scores during heel stick by different interventions ( $r= 0.48$ to $0.60$ , $P= 0.004$ to $0.03$ ).
Baudesson 2017*	PIPP/PIPP-R	DAN		“The comparisons between the two groups of the PIPP scores after the venipuncture and of the DAN scores during and after the venipuncture did not differ significantly”
Biran 2011*	DAN	PIPP/PIPP-R		Baseline DAN and PIPP scores were similar for the 2 interventions. For the S group and S+E group, respectively, the mean (SD) baseline DAN scores were 2.2 (2.4) and 2.1 (2.5) ( $P .843$ ) and the mean baseline PIPP scores were 4.2 (1.9) and 4.5 (2.2) ( $P .645$ ).
Carbajal 2005	DAN	PIPP/PIPP-R		Not compared
Chermont 2009	NFC	NIPS	PIPP/PIPP-R	The NFCS and NIPS scores for the 4 groups at the 4 study times (Tables 2 and 3) were analyzed by using repeated-measures MANOVA, with adjustment for mode of delivery, neonatal gender, birth weight, 5- minute Apgar score, hours of life, and minutes after feeding. There were associations of both scores with gender ( $P.008$ ), 5-minute Apgar score ( $P.030$ ), hours of life ( $P .001$ ), and minutes after feeding ( $.001$ ). After adjustment, the main effects of time and analgesic procedures were statistically significant ( $P.001$ ), as was the interaction between time and procedure ( $P.001$ ).  PIPP scores reported on their own.
Cignacco 2008	Bernese pain scale for neonates	PIPP/PIPP-R		Not compared
e Silva 2008*	COMFORT-neo	NIPS		Both infusions provided adequate analgesia and sedation, as demonstrated by the NIPS ( $<4$ ) and COMFORT scales ( $<20$ )
Gitto 2012*	NIPS	PIPP/PIPP-R		Melatonin treatment did not change the NIPS score either before, during, or after 5 min of elective endotracheal intubation. The



				PIPP score was, however, significantly lower at 24, 48, 72 hr and 7 days during mechanical ventilation in newborns treated with melatonin compared with infants treated with standard premedication, that is control newborns.
Johnston 1999	PIPP/PIPP-R	NFCS		Not compared
Johnston 2003	PIPP/PIPP-R	NFCS		Not compared
Johnston 2007	PIPP/PIPP-R	NFCS		Not compared
Lago 2008*	NIPS	PIPP/PIPP-R		Both pain scores were lower in the remifentanyl group than in the control group during skin preparation (mean differences NIPS $1.11 \pm 0.72$ , PIPP $2.19 \pm 0.86$ ) and needle puncture (mean differences NIPS $1.59 \pm 0.73$ , PIPP $2.44 \pm 0.87$ ).
Norman 2011	PIPP/PIPP-R	ALPS-neo	EDIN	Not compared
Patel 2003	PIPP/PIPP-R	NIPS		For prick pain, the PIPP and the NIPS scores correlate well with each other (Figure 1). The linear correlation coefficient between the two pain scores was 0.696, and the Pearson's correlation test showed that this correlation was statistically significant at $P=0.01$ .
Romantsik 2014	NFCS	BIIP		Crying duration correlated significantly with NFCS and BIIP scores during both the lance ( $r = 0.63$ and $0.44$ , respectively; $p < 0.0001$ ) and recovery periods ( $r = 0.67$ and $0.76$ , respectively; $p < 0.0001$ ).
Roofthoof 2017*	PIPP/PIPP-R	COMFORT-neo		PIPP scores were not different compared to the paracetamol groups (median = 8, IQR: 6.3–10; $p = 0.78$ ). Regression analysis showed that PIPP scores were comparable between the 4 treatment groups. NSAIDs added as a covariate did not significantly affect the PIPP scores ( $p = 0.60$ ) either.  The median COMFORTneo scores of the sucrose-treated patients were available for 16 patients and had a median of 12 (IQR: 10–14.8), and were not statistically different compared to the total paracetamol-treated patients ( $p = 0.08$ ).
Sato 2007	NFCS	NIPS		Both pain scales' scores showed a strong and significant difference between the groups.
Simons 2003	NIPS	PIPP/PIPP-R		The PIPP, NIPS, and VAS scores during suctioning were not predicted in multiple regression analyses by treatment group or by the amount of additional morphine used (TABLE 3). Mean NIPS and VAS scores decreased with increasing length of study, and VAS scores were lower in center 1 compared with center 2. Spearman $\rho$ correlation coefficients between the different pain

				scores were 0.44 (NIPS vs PIPP, P<.001), 0.31 (NIPS vs VAS, P<.001), and 0.22 (PIPP vs VAS, P=.02).
Simonse 2013	PIPP	COMFORTneo		The partial correlation (adjusted for treatment group) between the 2 pain assessment scales was 0.70.
Ullsten 2017	PIPP/PIPP-R	BIIP		Not compared
Perroteau 2018*	PIPP/PIPP-R	DAN		Each score, PIPP and DAN, was analysed for infants with or without non-invasive ventilation, and no difference in the median score was found (data not shown).
Kahraman 2018*	NIPS	COMFORT-neo		The COMFORTneo scores showed a significantly lower score in the prone position compared to supine position (p = 0.000). The COMFORTneo NRS-pain scores showed a significantly lower score in the prone position compared to the supine position (p = 0.000).
Tekgündüz 2019*	NIPS	PIPP/PIPP-R		The mean PIPP scores of the premature infants in the control group after the intervention ( $8.35 \pm 2.31$ ) were significantly higher than the scores of the infants in the lullaby and glucose groups ( $6.77 \pm 2.18$ and $6.82 \pm 2.27$ , respectively) (p < .05) (Table 6).  The mean NIPS scores of the premature infants in the control group during the intervention ( $5.67 \pm 0.81$ ) were significantly higher than those of the infants in the lullaby and glucose groups ( $5.17 \pm 0.92$ and $4.20 \pm 1.82$ , respectively) (p < .05).

\* = a statistical comparison between the scales was not reported

*Suuplementary table 3. Trials with more than one assessor that reported agreement between assessors (n=61, 54.9% of trials with more than one assessor). For full citations, see supplementary table 1.*

<b>Author, year</b>	<b>Number of assessors</b>	<b>Agreement between assessors</b>
Akcan 2016	2	ICC before and after heel lance 0.98 and 0.94, respectively.
Alemdar 2018	3	The result of the inter-observer agreement test both for the pain (Kendall = 0.673, $p > 0.05$ ) and comfort (Kendall = 0.713, $p > 0.05$ ).
Axelin 2006	2	Kappa coefficient 0.927.
Axelin 2009	2	Interrater reliability was 0.968 with NIPS and 0.986 with PIPP.
Badiee 2014	3	The inter-rater reliability was 0.9.
Biran 2011	2	The 2 independent observer nurses initially agreed on 75 of 76 DAN assessments and on 74 of 76 PIPP assessments. They then together assessed the 1 DAN and 2 PIPP conflicting assessments to reach a final common score.
Boyle 2006	2	Inter-observer reliability was >90%
Caglar 2017	2	Internal consistency of 0.74
Campbell-yeo 2012	Unclear	One coder coded the infants in cobedding care and another coder coded infants assigned to standard care. During the study period, intrarater reliability of coders, checked every 3 months, remained over 90%. At the end of the coding period, the coder who had coded infants in the standard care group, with over 90% agreement, recoded 6 videos from the cobedding group.
Carbajal 2003	2	There was good agreement between both observers on initial evaluation (Krippendorff's $r=92.7$ ).
Chermont 2009	2	Good agreement ( $k \geq 0.80$ ) between the 2 investigators for >80% of all items assessed for the 3 scales.
Cignacco 2012	4	Interrater reliability for the T-BPSN scores in this study averaged 99.2% for the 5 heel sticks (range: 98.8% for heel stick 1 and 99.8% for heel stick 5).
Cong 2011	2	Kappa coefficient 0.95.
Costa 2013	2	Kappa coefficient 0.70
Dur 2018	2	The consistency level of both observers was 98.7% during the procedure, which was statistically significant [Intraclass Correlation Coefficient (ICC): 0.987; $p < 0.01$ ].
Dekker 2019	2	A Cohen's $\kappa > 0.4$ was considered reasonable. When inter-rater reliability appeared to be $< 0.4$ , an additional NICU nurse assessed the same procedures to find reasonable reliability between two NICU nurses.
Efendi 2018	2	A Bland Altman test was carried out to test the interrater reliability of two experts and the result where 0.632 and 1.99 in the range of -5 to +5.
Gabriel 2013	3	Intraclass Correlation Coefficient (ICC) was $> 0.60$
Galderisi 2018	2	The agreement between the 2 PIPP score observers, assessed by Cohen $k$ scores, was 0.65, with the difference never $> 2$ points.

Gao 2018	2	the inter-rater reliability among evaluators was 97%.
Gaspardo 2008	2	The reliability coding between two trained and independent coders was carried out on 10% of the study sample, with a reliability coefficient of 93%.
Gibbins 2003	“Trained individuals”	Intrarater reliability was high ( $\alpha = 0.93$ )
Gradin 2002	4	Interobserver reliability was 0.81% using the intraclass correlation coefficient
Hartley 2018	Unclear	Intrarater reliability was 0.98 (95% CI 0.97–0.99) for heel lance PIPPR scores and 0.97 (0.94–0.99) for retinopathy of prematurity screening. Interrater reliability was 0.98 (0.95–0.99) for heel lance and 0.89 (0.79–0.95) for retinopathy of prematurity screening.
Hwang 2015	2	Internurse agreement was 91% ( $\kappa = 0.91$ ).
Jain 2000	2	For each feature of the NFCS, the coefficient of reliability between assessors was 0.96, 0.96, 0.94, 0.95, and 1.0 for eye squeeze, brow bulge, deepened nasolabial folds, open mouth, and cry respectively.
Jain 2001	2	The coefficient of reliability between the two assessors was 0.84, 0.87, 0.91, 0.88, and 0.94 for eye squeeze, brow bulge, deepened nasolabial folds, open mouth, and cry respectively.
Johnston 2009	2	Intrarater reliability was checked every 15 sessions and remained over 80%.
Johnson 2011	2	Intrarater reliability was checked every 3 months, remaining more than 90%.
Johnston 2012	2	Intrarater reliability was checked every 3 months and was maintained over 90%.
Johnston 2013	2	The overall reliability was ICC of 0.81, although 1 facial action often not seen because of adhesive tape obstruction (naso-labial furrow) was ICC 0.58.
Kahraman 2018	2	ICC 0.566-0.736
Karaca 2016	2	Observers’ evaluations were found consistent (for each of 6 categories of NIPS, Kappa observers consistency test gives the result in range of 0.48 and 0.71).
Kucukoglu 2015	4	A good level of concordance was found among the observers (Kappa = 0.65).
Kucukoglu 2016	2	In this study, the Cronbach alpha coefficient was found to be 0.71.
Larsson 1998a	2	Interobserver reliability was 91%
Larsson 1998b	2	The reliability was 95%, computed for 50% of the subjects (the first 25 in each group), for each variable in each time segment.
Ling 2005	2	Both the intra-rater (ICC 0.993 95% CI 0.988-0.996) and inter-rater (ICC 0.988 95% CI 0.980-0.993) agreement on the 3-minute NIPS score were good.
Long 2003	2	The coefficients of reliability between assessors for the NFCS scores were 0.87, 0.85, 0.94, 0.87, and 1.0 for brow bulge, eye squeeze, deepened naso-labial folds, open mouth, and cry, respectively.
McGinnis 2016	2	There was moderate to good agreement between the 2 raters. The weighted $\kappa$ value for baseline N-PASS scores was 0.34. The weighted $\kappa$ values for the other time points ranged from 0.60 to 0.61. There was moderate correlation between raters at each time point ( $r = 0.33-0.86$ ).
Murmu 2017	2	The observers achieved good inter-rater reliability rates of over 90%.
Nimbalkar 2013	2	The Inter-rater agreement for individual components of PIPP score was excellent with average weighted Kappa 0.84 (Range 0.79 to 0.86).

Obeidat 2015	2	Interrater reliability analysis of individual event scores of the PIPP scale yielded reliability coefficients of 0.92 to 0.95.
Okan 2007	2	The observers were trained with the NFCS method and interobserver reliability was 95%
Romantsik 2014	2	For all measures, interobserver (21 parallel measurements, a random sample of 10% of the data) and intra-observer (20 repeated measurements) reliability was >95%.
Roofthoof 2017	2	interrater reliability linearly weighted Cohen's $\kappa$ >0.65
Saththasivam 2009	2	The inter-rater reliability was 80%
Şener Taplak 2017	3	Inter-observer consistency analysis was performed for each item of the PIPP after the specialists had assessed the pain and determined the PIPP scores of all the preterm infants, which ranged between 0.90 and 1.00.
Sharara-Chami 2017	2	$\kappa = 0.843$
Shrestha 2012	2	There was a high interobserver reliability (Pearson correlation coefficient, $r=0.977$ ).
Simons 2003	2	Interrater reliability (intraclass correlation coefficient of 0.70 and 0.73 for the NIPS and PIPP, respectively, and 0.67 for the VAS score.
Simonse 2012	3	The ICC estimated from the measurements taken by the 3 investigators was 0.95 for the PIPP score and 0.82 for the COMFORTneo scale.
Slater 2010	2	Bland-Altman plots showed good reliability with little bias (intra-rater bias 0.07; inter-rater bias 0.73). The limits of agreement for the intra-rater re-test were $\pm 1.62$ . The limits of agreement for the inter-rater comparison were $\pm 1.49$ .
South 2005	3	The weighted kappa for intrarater reliability was 0.73 to .85, and for interrater reliability was 0.43 to 0.64.
Stevens 2018	2	An inter-rater reliability >0.9 was achieved on a random sample of 5 neonates, early in the study and with each 25% of data collected.
Tekgündüz 2019	4	The coefficient of concordance among the observers was calculated and was found to be at a good level ( $\kappa$ value = 0.67).
Thakkar 2016	2	Interobserver reliability was >90%.
Tinner 2013	2	he correlation of BPSN scores after heel pricks between nurses and the single reviewer (Spearman rank order coefficient) was 0.798 ( $P < .001$ ),
Uyan 2005	2	The correlation between the two observers was high and statistically significant ( $r = 0.89; 0.89; 0.93; 0.98$ and $P = 0.00; 0.00; 0.00; 0.00$ for 0, 1, 2 and 3 min, respectively).
Weatherstone 1993	"Blinded observers"	Interobserver reliability of scoring on the first eight categories was tested between observers on 10 subjects with an average of 87.5%
Yilmaz 2011	2	Kappa reliability test showed inter-observer reliability (0.84).

### Embase

No. Query Results

#13. #12 AND [abstracts]/lim

#12. #10 AND ('article'/it OR 'article in press'/it) AND ([english]/lim OR [italian]/lim OR [swedish]/lim)

#11. #10 AND ('Article'/it OR 'Article in Press'/it)

#10. #5 AND #9

#9. #6 OR #7 OR #8

#8. clinical:ti,ab AND study:ti,ab

#7. clinical:ab,ti AND trial:ab,ti

#6. 'clinical study'/exp OR 'clinical study' OR 'clinical trial'/exp OR 'clinical trial' OR randomized:ti,ab OR randomised:ti,ab OR multicenter:ti,ab OR observational:ti,ab

#5. #1 AND #4

#4. #2 OR #3

#3. 'pain assessment'/exp OR 'pain measurement'

#2. pain AND (assess\* OR score\* OR scale\* OR tool\*)

#1. 'newborn'/exp OR newborn OR newborns OR 'neonate'/exp OR neonate OR neonates

### PubMed

#1 ("Infant, Newborn"[Mesh] OR newborn OR newborns OR neonate OR neonates)

#2 ((pain AND (assess\* OR score\* OR scale\* OR tool\*)) OR "Pain Measurement"[Mesh] OR "pain measurement")

#3 (((((clinical[Title/Abstract] AND study[Title/Abstract])) OR (clinical[Title/Abstract] AND trial[Title/Abstract]))) OR ("Clinical Trial"[Publication Type] OR "Clinical Studies as Topic"[Mesh] OR "clinical study" OR "clinical trial")) OR ((randomized[Title/Abstract] OR randomised[Title/Abstract] OR multicenter[Title/Abstract] OR observational[Title/Abstract]))

#4 #1 AND #2 AND #3

#5 Limit to English, Italian, Swedish

#6 Filter: has abstract

## Cinahl Complete

S10 Limit to Academic journals

S9 S1 AND S4 AND S7

S8 S1 AND S4 AND S7

S7 ( (MH "Clinical Trials+") OR "clinical study" OR "clinical trial" ) OR ( randomized OR randomised OR multicenter OR observational ) OR ( (clinical AND study) OR (clinical AND trial) )

S6 (MH "Clinical Trials+")

S5 S1 AND S4

S4 S2 OR S3

S3 pain AND ( (assess\* OR score\* OR scale\* OR tool\*) )

S2 (MH "Pain Measurement") OR "pain measurement"

Limiters - Language: English, Swedish

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

Search modes - Find all my search terms

S1 (MH "Infant, Newborn+") OR newborn OR newborns OR neonate OR neonates

Search modes - Find all my search terms



## PsycInfo

<a href="#">Search ID#</a>	Search Terms	Search Options	Actions
<input type="checkbox"/> S7	S1 AND S2 AND S5	Narrow by: - English, Academic Journals	
<input type="checkbox"/> S6	S1 AND S2 AND S5	Search modes - Find all my search terms	
<input type="checkbox"/> S5	S3 OR S4	Search modes - Find all my search terms	
<input type="checkbox"/> S4	( clinical AND trial ) OR ( clinical AND study )	Search modes - Find all my search terms	
<input type="checkbox"/> S3	DE "Clinical Trials" OR "clinical study" OR "clinical trial" OR randomized OR randomised OR multicenter OR observational	Search modes - Find all my search terms	
<input type="checkbox"/> S2	newborn OR newborns OR neonate OR neonates	Search modes - Find all my search terms	
<input type="checkbox"/> S1	( (DE "Pain Measurement") OR (DE "Pain Thresholds") ) OR "pain measurement" OR ( pain AND ( assess* OR score* OR scale* OR tool* ) )	Search modes - Find all my search terms	

## Scopus

#1 TITLE-ABS-KEY ( newborn OR newborns OR neonate OR neonates )

#2 ( TITLE-ABS-KEY ( pain W/5 ( assess\* OR score\* OR scale\* OR tool\* ) ) OR TITLE-ABS-KEY ( "pain measurement" ) )

#3 ( TITLE-ABS-KEY ( clinical W/5 study ) OR TITLE-ABS-KEY ( clinical W/5 trial ) OR TITLE-ABS-KEY ( randomized OR randomised OR multicenter OR observational ) )

#4 #1 AND #2 AND #3

#5 Limit to ( DOCTYPE , "article" )

#6 LIMIT-TO ( LANGUAGE , "English" ) OR LIMIT-TO ( LANGUAGE , "Italian" ) OR LIMIT-TO ( LANGUAGE , "Swedish" )

## **Cochrane Library**

#1 MeSH descriptor: [Infant, Newborn] explode all trees

#2 neonate or neonates or newborn or newborns

#3 #1 OR #2

#4 MeSH descriptor: [Pain Measurement] explode all trees

#5 pain near/4 (assess\* or score\* or scale\* or tool\*):ti,ab,kw (Word variations have been searched)

#6 #4 OR #5

#7 MeSH descriptor: [Clinical Studies as Topic] explode all trees

#8 clinical near/5 study:ti,ab,kw or clinical near/5 trial:ti,ab,kw or randomized or randomised or multicenter or observational:ti,ab,kw (Word variations have been searched)

#9 #7 OR #8

#10 #3 AND #6 AND #9

#11 Limit to Trials

## **Searches**

PubMed, 1 March 2019

Embase, 1 March 2019

Cinahl, 12 March 2019

PsycInfo, 12 March 2019

Scopus, 12 March 2019

## DATA EXTRACTION SHEET

ID	
Name of first author (last name, initial)	
Year of publication	
Pain-scale used in the study (primary outcome if defined)	
More than one pain scales reported in the same study?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, write the names of additional pain scales reported	
If yes, were the two scales compared by study authors?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was the pain scale assessed independently by 2 people?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss <input type="checkbox"/> Yes, for a subset of observations
More than 2 people?	<input type="checkbox"/> Yes, # <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was agreement between two assessors reported?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Country of origin	
Assessment by	<input type="checkbox"/> Emma <input type="checkbox"/> Hanna <input type="checkbox"/> Mats

	<input type="checkbox"/> Annan
Is the study design a trial? <sup>1</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Is there a control group or control condition (e.g. cross-over)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
How many newborns were enrolled? (Intervention – Control)	
How many were included in the result reporting?	
Is the study sponsored by a pharmacological company?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Is it reported in the methods if the protocol was registered in advance?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If an intervention, what type?	<input type="checkbox"/> Pharmacological (including sweet solution) <input type="checkbox"/> Non-pharmacological <input type="checkbox"/> Combined/other
Specify the intervention (e.g. name of drug)	
Did it include preterm newborns?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Did it include full term newborns?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Gestational age (at birth) of included newborns (give all information)	Total                  Interv                  Contr
Postnatal age at intervention	Total                  Interv                  Contr
...or post-conceptual age at intervention	Total                  Interv                  Contr

<sup>1</sup> NIH Definition of a Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Birth weight of included newborns (give all information)	Total	Interv	Contr
Were newborns in the hospital settings? If no, specify	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Were newborns in a neonatal unit? If no, specify	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
What was the income level <sup>2</sup> in the country of the study?	<input type="checkbox"/> High	<input type="checkbox"/> Middle	<input type="checkbox"/> Low
Were newborns sedated? (other drug than study drug) If yes, specify	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was the study on chronic/on-going pain?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was the study on procedural pain?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was the study on post-operative pain?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Special situations, e.g. sedated infants, hypo-therm infants, asphyxiated infants or other affection on the brain (cerebral haemorrhage)			
Source of pain	<input type="checkbox"/> Heel lance <input type="checkbox"/> Arterial puncture <input type="checkbox"/> S.c. injection <input type="checkbox"/> E.t. suctioning <input type="checkbox"/> Bladder puncture <input type="checkbox"/> Lumbar puction <input type="checkbox"/> Post-operative	<input type="checkbox"/> Venepuncture <input type="checkbox"/> Long line insert <input type="checkbox"/> I.m. injection <input type="checkbox"/> Tape removal <input type="checkbox"/> Eye examinat <input type="checkbox"/> Thoracic drain	

<sup>2</sup> <https://data.worldbank.org/country>

	<input type="checkbox"/> Other, specify
Was pain measured with more methods than pain scales? (e.g. cortical NIRS, biomarkers...)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, specify	
Was the chosen pain scale supported by validity and reliability data reported or a reference reported in the text?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, specify	<input type="checkbox"/> Referring to other studies <input type="checkbox"/> Reliability and validity testing within study
Was the measurement timeline and follow-up (when) reported (e.g., outcome was assessed at 1 and 4 hours following the painful procedure)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, specify	
Was it reported in the methods who assessed the outcomes (who) (e.g., nurse, parent)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, specify	<input type="checkbox"/> Nurse <input type="checkbox"/> Physician <input type="checkbox"/> Parent  <input type="checkbox"/> Other <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
Was it reported in the methods how the process to protect against bias was done? <sup>3</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If yes, specify	

<sup>3</sup> Types of bias, see e.g. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2917255/>

Was the pain assessed in blinding?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Discuss
If Yes, which type of blinding is reported? -> those administering treatment	
If Yes, which type of blinding is reported? -> those assessing the outcome	
If Yes, which type of blinding is reported? -> Data analysis	
Notes	
Assessor's suggestion	<input type="checkbox"/> Include <input type="checkbox"/> Exclude
Final decision	<input type="checkbox"/> Include <input type="checkbox"/> Exclude