

Appendix 1. The P5 Working Group

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Appendix 2. Secondary Continuous Outcomes

Secondary continuous outcomes	Progesterone + Pessary		Progesterone		Adjusted IRR (95%CI)	Adjusted p-value
	Mean/Median	SD/IQR	Mean/Median	SD/IQR		
Maternal length of stay in hospital	3	2-4	3	2-4	1.05 (0.94-1.16)	0.394
Neonatal length of stay in NICU	8.5	5-20.5	9.5	3-21	1.26 (0.87-1.82)	0.225
Gestational age at birth (weeks)	37.4	3.2	36.9	4.0		0.006
Birthweight (g)	2788.2	726.7	2759.6	829		0.077
5-minute Apgar score	9	9-10	9	9-10		0.763

IRR = Incident Rate Ratio

Appendix 3. Compliance of Pessary Use

Compliance Pessary	N	%
Removal according to the protocol	415	87.4
Gestational Age 36w	316	66.5
Painful contractions/ Labour	78	16.4
PROM	21	4.4
Removal not according to the protocol	60	12.6
Pain	11	2.3
Vaginal Discharge	8	1.7
Technical difficulties/ pessary not in place	4	1.1
Participant request	4	0.8
Vaginal bleeding	1	0.2
Other: medical indication, clinical condition	3	0.6
Not inserted	18	3.6
Missing information	11	2.3
Total	475	

Appendix 4. Post Hoc Subgroup Analyses for Preterm Birth before 37, 34, 32, 30, or 28 Weeks of Gestation

	Progesterone + Pessary		Progesterone		Adjusted RR (95% CI)	Adjusted p-value	p-value interaction
	n/N	%	n/N	%			
Overall preterm delivery < 37 weeks							
Multiple pregnancy							0.787
No	104/431	24.1	119/430	27.7	0.87 (0.70 - 1.09)	0.242	
yes	34/43	79.1	25/28	89.3	0.89 (0.72 - 1.08)	0.239	
Cervical length							0.663
>25mm	54/214	25.2	54/212	25.5	0.99 (0.72 - 1.37)	0.411	
<=25mm	84/260	32.3	90/246	36.6	0.88 (0.69 - 1.12)	0.153	
Parity							0.104
Nulliparous	61/251	24.3	81/249	32.5	0.71 (0.55 - 0.93)	0.014	
Multiparous	77/223	34.5	63/209	30.1	1.02 (0.78 - 1.33)	0.88	
Overall preterm delivery < 34 weeks							
Multiple pregnancy							0.635
No	33/431	7.7	52/430	12.1	0.63 (0.42 - 0.96)	0.027	
yes	14/43	32.6	12/28	42.9	0.76 (0.41 - 1.39)	0.425	
Cervical length							0.297
>25mm	13/214	6.1	13/212	6.1	0.99 (0.47 - 2.09)	0.648	
<=25mm	34/260	13.1	51/246	20.7	0.63 (0.42 - 0.94)	0.009	
Parity							0.054
Nulliparous	18/251	7.2	40/249	16.1	0.44 (0.26 - 0.75)	0.002	
Multiparous	29/223	13.0	24/209	11.5	0.87 (0.52 - 1.48)	0.616	
Overall preterm delivery < 32 weeks							
Multiple pregnancy							0.380
No	22/431	5.1	36/430	8.4	0.61 (0.36 - 1.02)	0.05	
yes	5/43	11.6	9/28	32.1	0.36 (0.14 - 0.97)	0.076	
Cervical length							0.257
>25mm	7/214	3.3	7/212	3.3	0.99 (0.35 - 2.78)	0.686	
<=25mm	20/260	7.7	38/246	15.4	0.50 (0.30 - 0.83)	0.004	
Parity							0.116
Nulliparous	11/251	4.4	30/249	12.0	0.35 (0.18 - 0.71)	0.003	
Multiparous	16/223	7.2	15/209	7.2	0.76 (0.38 - 1.54)	0.451	
Overall preterm delivery < 30 weeks							
Multiple pregnancy							0.355
No	15/431	3.5	26/430	6.0	0.58 (0.31 - 1.07)	0.069	

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yes	4/43	9.3	9/28	32.1	0.29 (0.10 - 0.85)	0.087	
Cervical length							0.524
>25mm	4/214	1.9	5/212	2.4	0.79 (0.22 - 2.91)	0.367	
<=25mm	15/260	5.8	30/246	12.2	0.47 (0.26 - 0.86)	0.008	
Parity							0.124
Nulliparous	7/251	2.8	23/249	9.2	0.29 (0.12 - 0.70)	0.006	
Multiparous	12/223	5.4	12/209	5.7	0.74 (0.33 - 1.67)	0.474	
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Overall preterm delivery < 28 weeks							
Multiple pregnancy							0.478
No	8/431	1.9	18/430	4.2	0.44 (0.19 - 1.01)	0.042	
yes	2/43	4.7	7/28	25.0	0.19 (0.04 - 0.83)	0.153	
Cervical length							0.387
>25mm	3/214	1.4	4/212	1.9	0.74 (0.17 - 3.28)	0.262	
<=25mm	7/260	2.7	21/246	8.5	0.32 (0.14 - 0.73)	0.007	
Parity							0.277
Nulliparous	4/251	1.6	17/249	6.8	0.24 (0.07 - 0.81)	0.021	
Multiparous	6/223	2.7	8/209	3.8	0.59 (0.22 - 1.62)	0.306	

Appendix 5. Post Hoc Analysis in High-Effect Subgroup

High- effect subgroup: singleton, cervix length <25mm, (n=464)

Outcome	Progesterone + Pessary		Progesterone		Adjusted RR (95% CI)	Adjusted p-value
	n/N	%	n/N	%		
Primary outcome (maternal level)	47/230	20.4	52/215	24.2	0.85 (0.61 - 1.19)	0.344
Overall preterm delivery < 37 weeks	64/233	27.5	73/228	32.0	0.87 (0.66- 1.14)	0.317
Overall preterm delivery < 34 weeks	24/233	10.3	42/228	18.4	0.57 (0.36 - 0.89)	0.014
Overall preterm delivery < 32 weeks	16/233	6.9	31/228	13.6	0.51 (0.29 - 0.89)	0.017
Overall preterm delivery < 30 weeks	12/233	5.2	23/228	10.1	0.51 (0.27 - 0.98)	0.045
Overall preterm delivery < 28 weeks	6/233	2.6	15/228	6.6	0.38 (0.16 - 0.93)	0.034

High- effect subgroup: nulliparous, cervix length ≤25mm, singleton (n=257)

Outcome	Progesterone + Pessary		Progesterone		Adjusted RR (95% CI)	Adjusted p-value
	n/N	%	n/N	%		
Primary outcome (maternal level)	20/127	15.8	33/120	27.5	0.59 (0.37 - 0.94)	0.025
Overall preterm delivery < 37 weeks	27/128	21.1	43/127	33.9	0.65 (0.44 - 0.97)	0.034
Overall preterm delivery < 34 weeks	9/128	7.0	26/127	20.5	0.35 (0.17 - 0.70)	0.003
Overall preterm delivery < 32 weeks	6/128	4.7	21/127	16.5	0.28 (0.12 - 0.67)	0.004
Overall preterm delivery < 30 weeks	4/128	3.1	14/127	11.0	0.28 (0.10 - 0.81)	0.019
Overall preterm delivery < 28 weeks	2/128	1.6	9/127	7.1	0.21 (0.05 - 0.95)	0.042

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