

Supplementary Online Content

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3 Saccone G, Maruotti GM, Giudicepietro A, Martinelli P. Effect of cervical pessary on
4 spontaneous preterm birth in women with singleton pregnancies and short cervical
5 length: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2017.18956

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7 **eTable 1.** Results of Vaginal Swabs at Randomization

8 **eTable 2.** Post Hoc Secondary Outcomes

9 **eTable 3.** Subgroup Analyses for Spontaneous Preterm Birth at Less Than 34 Weeks

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11 This supplementary material has been provided by the authors to give readers
12 additional information about their work.

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15 **eTable 1.** Results of Vaginal Swabs at Randomization
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Vaginal swabs	Pessary group N=150		Control group N=150	
Positive vaginal swab at randomization n (%)	36 (24.0%)		41 (27.3%)	
Antibiotics for positive vaginal swab n (%)	33 (22.0%)		38 (25.3%)	
Abnormal results	n	Antibiotic therapy n	n	Antibiotic therapy n
Bacterial vaginosis	30	30	34	34
Candida	3	0	3	0
Escherichia coli	1	1	2	2
Ureoplasma	1	1	1	1
Group B streptococcus	1	1	1	1

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 18 *Data are presented as number (percentage).*
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20 **eTable 2.** Post Hoc Secondary Outcomes
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	Pessary group N=150	Control group N=150	Between group difference in % (95% CI)	RR (95% CI)	<i>p</i>-value***
Overall preterm birth <37 weeks	35 (23.3%)	53 (35.3%)	-12.0 (-22.5 to -1.2)	0.66 (0.46 to 0.95)	0.03
Overall preterm birth <34 weeks	14 (9.3%)	26 (17.3%)	-8.0 (-16.1 to -0.1)	0.54 (0.29 to 0.99)	0.04
Overall preterm birth <32 weeks	11 (7.3%)	15 (10.0%)	-2.7 (-4.2 to +9.7)	0.73 (0.35 to 1.54)	0.54
Overall preterm birth <28 weeks	7 (4.7%)	9 (6.0%)	-1.3 (-4.4 to +7.1)	0.78 (0.30 to 2.03)	0.80
Iatrogenic preterm birth <34 weeks	3 (2.0%)*	3 (2.0%)**	0 (-4.1 to +4.1)	1.00 (0.21 to 4.88)	1.00
Birth weight <2,500 grams	28 (18.7%)	45 (30.0%)	-11.3 (-1.1 to +21.2)	0.62 (0.41 to 0.94)	0.03
Birth weight <1,500 grams	10 (6.7%)	15 (10.0%)	-3.3 (-3.5 to +10.2)	0.67 (0.31 to 1.44)	0.40
Necrotizing enterocolitis	3 (2.0%)	4 (2.7%)	-0.7 (-3.5 to +5.0)	0.75 (0.17 to 3.29)	0.99
Intraventricular hemorrhage grade 3 or 4	4 (2.7%)	6 (4.0%)	-1.3 (-3.5 to +6.2)	0.67 (0.19 to 2.31)	0.75
Respiratory distress syndrome	14 (9.3%)	31 (20.7%)	-11.4 (-19.9 to -2.9)	0.45 (0.25 to 0.81)	0.01
Bronchopulmonary dysplasia	8 (5.3%)	12 (8.0%)	-2.7 (-3.5 to +9.0)	0.67 (0.28 to 1.58)	0.49
Retinopathy of prematurity requiring therapy	1 (0.7%)	9 (6.0%)	-5.3 (-10.4 to -0.9)	0.11 (0.01 to 0.87)	0.02
Blood-culture proven sepsis	9 (6.0%)	13 (8.7%)	-2.7 (-3.8 to +9.3)	0.69 (0.31 to 1.57)	0.50

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 23 *Data are presented as number (percentage).*
 24 *RR, relative risk; CI, confidence interval; Overall preterm birth, either spontaneous or indicated*
 25 *preterm birth*
 26 *No adjustment for multiple comparisons was made, so the findings of the secondary outcomes*
 27 *should be considered exploratory.*
 28 *Boldface data, statistically significant*
 29 **One for nonreassuring fetal heart rate at nonstress test, and two for preeclampsia*
 30 ***One for intrauterine growth restriction, and two for preeclampsia*
 31 **** chi-square test with continuity correction*
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33 **eTable 3.** Subgroup Analyses for Spontaneous Preterm Birth at Less Than 34 Weeks
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	Pessary group	Control group	Between group difference % (95% CI)	RR (95% CI)	p-value*	Test of interaction p-value**
Progesterone therapy	10/133 (7.5%)	21/125 (16.8%)	-9.3 (-17.7 to -1.0)	0.45 (0.22 to 0.91)	0.04	0.56
No progesterone therapy	1/17 (5.9%)	2/25 (8.0%)	-2.1 (-21.8 to +21.0)	0.74 (0.07 to 7.48)	0.99	
TVU CL ≤10mm	3/56 (5.4%)	10/42 (23.8%)	-18.4 (-34.6 to -3.3)	0.23 (0.07 to 0.77)	0.02	0.46
TVU CL >10mm	8/94 (8.5%)	13/108 (12.0%)	-3.5 (-5.8 to +12.5)	0.71 (0.31 to 1.63)	0.56	

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 36 *Data are presented as number/total number (percentage).*

37 *Boldface data, statistically significant*

38 *SPTB, spontaneous preterm birth; RR, relative risk; CI, confidence interval; TVU CL,*
 39 *transvaginal ultrasound cervical length*

40 ** chi-square test with continuity correction*

41 ***Wald test*

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