

Progesterone in threatening miscarriage – the PRISM trial

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 - Presented by Gerhard Hanekom

Clinical Problem

- PROMISE Trial – The role of progesterone in recurrent miscarriages
 - NEJM 2015
 - Negative result – P does not improve outcome in pts with RPL

| | | | | |
|--|----------------|----------------|------------------|------|
| Stillbirth | 1/398 (0.3) | 2/428 (0.5) | 0.54 (0.05–5.92) | 0.61 |
| Live birth after 24 weeks 0 days of gestation† | 262/398 (65.8) | 271/428 (63.3) | 1.04 (0.94–1.15) | 0.45 |
| Twin live births after 24 weeks 0 days of gestation† | 4/398 (1.0) | 5/428 (1.2) | 0.86 (0.23–3.18) | 0.82 |

| Number of previous losses | Progesterone Live birth / total (%) | Placebo Live birth / total (%) | Increase in live births | p-value |
|---------------------------|-------------------------------------|--------------------------------|-------------------------|---------|
| 3 | 148/218 (67.9%) | 159/236 (67.4%) | +0.5% | 0.91 |
| 4 | 61/82 (74.4%) | 70/103 (68.0%) | +6.4% | 0.33 |
| 5 | 28/55 (50.9%) | 21/48 (43.8%) | +7.1% | 0.47 |
| 6 or more | 27/47 (57.4%) | 20/40 (50.0%) | +7.4% | 0.49 |

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Clinical Problem continued...

**Fertility
and Sterility.**



Ogasawara M et al,
Fert Steril 2000

Outcome (%)



Methods

- Study design
 - Randomized, double blind, placebo-controlled
- Population
 - Women with early pregnancy bleeding
- Intervention
 - 400mg progesterone taken vaginally twice daily till 16w
- Comparison
 - Placebo
- Main outcome
 - Live birth beyond 34w

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Results

- n=4153
- Overall: LBR 75% vs 72% - p=0.08 (borderline)
- BUT:
 - Subgroup effect:

| Number of previous miscarriages | Progesterone | Placebo | RR (95% CI) |
|---|--------------------------|--------------------------|---------------------------------------|
| 0 | 824/1111 (74%) | 840/1127 (75%) | 0.99 (0.95, 1.04) p=0.71 |
| 1-2 | 591/777 (76%) | 534/738 (72%) | 1.05 (1.00, 1.12) p=0.07 |
| >=3 | 98/137 (72%) | 85/148 (57%) | 1.28 (1.08, 1.51) p=0.004 |
| Any number of previous miscarriages (=>1) | 689/914 (75%) | 619/886 (70%) | 1.09 (1.03 – 1.15) P=0.003 |

Putting this to practice

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