Jim Thornton's prediction of the PRISM trial result. (#12962)

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1) Have any data been collected for this study already?
It's complicated. We have already collected some data but explain in Question 8 why readers may consider this a valid pre-registration nevertheless.

2) What's the main question being asked or hypothesis being tested in this study?
The PRISM trial. Details Here. http://www.isrctn.com/ISRCTN14163439 The chief investigator Arri Coomarasamy has told me on Friday 28 July 2018 that the unblinded data have been analysed and the results are in. I asked him to not tell me the result until I had registered my prediction here.

3) Describe the key dependent variable(s) specifying how they will be measured.
Live birth beyond 34 weeks

4) How many and which conditions will participants be assigned to?
Two. progesterone or placebo

5) Specify exactly which analyses you will conduct to examine the main question/hypothesis.
Estimation of relative risk and 95% CI for primary outcome. Rrimary analysis adjusted for minimisation factors only. MCID a 5% increase in live birth rate after 34 week.

6) Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations.
analysis by intention to treat.

7) How many observations will be collected or what will determine sample size? No need to justify decision, but be precise about exactly how the number will be determined.
4150 patients with threatened miscarriage. divided equally into two groups.

8) Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?)
Jim Thornton predicts that the result will be negative. i.e. that the point estimate for any beneficial effect will be smaller that the predefined delta, i.e. any improvement in live birth will be smaller than 5%. I also predict that the statistical significance level of the primary analysis will be greater than 0.05.

If my prediction above is wrong, I will believe the result and encourage the use of progesterone for this clinical indication.

Note, although the data have been collected and analysed I have not seen the result. Arri Coomarasamy will certify that this prediction is made before he told me.