

# Progesterone to prevent miscarriage in women with early pregnancy bleeding: the PRISM RCT

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## Plain English summary

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## Plain English summary

Miscarriage is a common complication of pregnancy that affects one in five pregnancies. Several small studies have suggested that progesterone, a hormone essential for maintaining a pregnancy, may reduce the risk of miscarriage in women presenting with early pregnancy bleeding.

This research was undertaken to test whether or not progesterone given to pregnant women with early pregnancy bleeding would increase the number of live births when compared with placebo (dummy treatment).

The women participating in the study had an equal chance of receiving progesterone or placebo, as determined by a computer; one group received progesterone (400 mg twice daily as vaginal pessaries) and the other group received placebo with an identical appearance. Treatment began when women presented with vaginal bleeding, were < 12 weeks of gestation and were found to have at least a pregnancy sac on an ultrasound scan. Treatment was stopped at 16 weeks of gestation, or earlier if the pregnancy ended before 16 weeks. Neither the participants nor their health-care professionals knew which treatment was being received.

In total, 23,775 women were screened and 4153 women were randomised to receive either progesterone or placebo pessaries. Altogether, 2972 participants had a live birth after at least 34 weeks of gestation. Overall, the live birth rate in the progesterone group was 75% (1513 out of 2025 participants), compared with 72% (1459 out of 2013 participants) in the placebo group. Although the live birth rate was 3% higher in the progesterone group than in the placebo group, there was statistical uncertainty about this finding. However, it was observed that women with a history of one or more previous miscarriages and vaginal bleeding in their current pregnancy may benefit from progesterone. For women with no previous miscarriages, our analysis showed that the live birth rate was 74% (824 out of 1111 participants) in the progesterone group compared with 75% (840 out of 1127 participants) in the placebo group. For women with one or more previous miscarriages, the live birth rate was 75% (689 out of 914 participants) in the progesterone group compared with 70% (619 out of 886 participants) in the placebo group. The potential benefit appeared to be most strong for women with three or more previous miscarriages, who had a live birth rate of 72% (98 out of 137 participants) in the progesterone group compared with 57% (85 out of 148 participants) in the placebo group. Treatment with progesterone did not appear to have any negative effects.

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