

# **PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages – a randomised, double-blind, placebo-controlled, international multicentre trial and economic evaluation**

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## Plain English summary

### **The PROMISE trial and economic evaluation**

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## Plain English summary

Progesterone is a natural hormone that is essential to maintain a healthy pregnancy, and previous research has suggested an association between lower levels of progesterone and higher rates of miscarriage. This trial was undertaken to test whether or not progesterone given to pregnant women with a history of repeated (three or more, consecutive or non-consecutive) unexplained early pregnancy losses would increase the number of pregnancies leading to live births after at least 24 weeks of gestation, when compared with placebo (a dummy drug). A pregnancy loss is considered to be unexplained if conditions known to increase the risk of miscarriage are absent.

The treatment that each participant in the study received was decided at random by a computer; one group received progesterone (400 mg twice daily as vaginal capsules) and the other group received placebo with an identical appearance, from soon after a positive urinary pregnancy test, and no later than 6 weeks of pregnancy, until 12 completed weeks of pregnancy (or earlier if the pregnancy ended before 12 weeks).

In total, 836 women received the treatment. Altogether, 533 women experienced a live birth after at least 24 weeks of pregnancy. The live birth rate in the progesterone group was 65.8%, compared with 63.3% in the placebo group (women who took the dummy treatment). The difference between these live birth rates is not statistically significant, which suggests that progesterone therapy in the first trimester is of no benefit for women with unexplained repeated pregnancy loss.

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