

# Does progesterone prophylaxis to prevent preterm labour improve outcome? A randomised double-blind placebo-controlled trial (OPPTIMUM)

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## Plain English summary

### The OPPTIMUM RCT

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## Plain English summary

Progesterone is widely used to prevent preterm birth (birth of the baby before 37 weeks' gestation), but it has not been approved by government bodies for this purpose. Additionally, we do not know how progesterone will affect the baby in the longer term. We wanted to find out what effect progesterone given to women at high risk of preterm birth would have on rates of preterm birth, the health of the newborn baby and the health of the offspring at the age of 2 years.

In total, 1197 women at risk of preterm birth helped with the study. We did a test to look at the risk of preterm birth in those who agreed. We gave half of the women who were at increased risk progesterone and the other half a dummy treatment (placebo). Neither the women nor the researchers knew which treatment the women were getting until the end of the study. We recorded how long pregnancy lasted and the health of the baby shortly after birth and at 2 years of age.

We found that progesterone had no significant benefits or harms on either the rate of preterm birth or the health of the baby. This means that progesterone might not be helpful for women at risk of preterm birth. This information should be considered by expert groups making guidelines and doctors advising pregnant women, and needs to be discussed with pregnant women considering taking it. Potentially, this research could prevent the exposure of large numbers of pregnant women and their babies to unnecessary progesterone.



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