Evaluating Hormone Treatments for Women at Increased Risk for Preterm Birth – EPPPIC

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What was the research about?
A full-term pregnancy lasts about 40 weeks. In preterm birth, a baby is born before 37 weeks. When babies are born too soon, they are at higher risk for health problems, like difficulty breathing or feeding. Babies who are born before 34 weeks are also more likely than full-term babies to die during their first year.

Progestogens are hormones made by women’s bodies that help support pregnancy. They may help reduce the risk of preterm birth. In this study, the research team analyzed data from 30 previous studies to examine two types of hormone treatments for pregnant women who were at risk for preterm birth:

- **17-OHPC**, a hormone made in a lab and injected
- **Vaginal progesterone**, a natural hormone given through a gel or tablet in the vagina

What were the results?
Women pregnant with one baby. Compared with getting no hormones, women with a short cervix or previous preterm birth who received either 17-OHPC or vaginal progesterone

- Had a lower chance of their baby being born before 34 weeks
- Might have a lower chance of their baby dying or having serious problems
- Might have more health problems

The study found no evidence that either 17-OHPC or vaginal progesterone was better than the other in reducing

- Preterm birth before 34 weeks
- Women’s health problems
- Newborns’ health problems

Women pregnant with twins or triplets. Compared with no hormones, the study found no evidence that either 17-OHPC or vaginal progesterone reduced the chances of preterm birth before 34 weeks, or women’s or newborns’ health problems for women with no other risk factors.

Who was in the study?
Researchers analyzed 30 trials, which included 9,936 women at increased risk for preterm birth and their 14,477 babies. Most women who were pregnant with one baby either had a previous preterm birth or a short cervix. Most women who were pregnant with twins or triplets didn’t have other risk factors.

What did the research team do?
The research team combined data from the trials and analyzed it together. Combining data from multiple trials provides more reliable results that just looking at single trials. The team compared the treatments to no treatment and to each other using these data, to see how well they reduced preterm birth and women’s and babies’ health problems.
Women who had given birth preterm and members of patient and family advocacy organizations gave input on the study.

**What were the limits of the study?**

The research team could not be certain about the treatments’ effects on serious problems for babies or mothers, as these problems happened only rarely in the trials. Also, only two trials directly compared 17-OHPC and vaginal progesterone.

After the team completed their analysis, other researchers published results from a large trial looking at women receiving 17-OHPC. If this trial was included, the study results for 17-OHPC might change. Future research could update the study with results from this large trial.

**How can people use the results?**

Doctors and women at risk for preterm birth can use these results when talking about options to help reduce the chance of their babies being born preterm.

*To learn more about this project, visit [www.pcori.org/Stewart297](http://www.pcori.org/Stewart297).*