

Progesterone injections do not prevent preterm birth in twin pregnancies

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Weekly progesterone injections do not prevent premature births in women pregnant with twins, a University of North Carolina at Chapel Hill study has found.

The result came as a surprise to the researchers, who previously discovered that weekly injections of the naturally occurring hormone, called 17 alpha-hydroxyprogesterone or 17-OHPC, reduced additional preterm births by one-third in women whose previous babies were born prematurely.

“Based on the results of the first study, which showed that 17-OHPC reduced preterm birth in the group with the highest risk, we were hopeful that it would also prevent preterm birth in twin pregnancies, which represents an intermediate level of risk,” said John Thorp, M.D., a study co-author and professor of obstetrics and gynecology UNC-Chapel Hill. “The mechanisms that lead to preterm birth are complex, and I think our current study shows they may not be amenable to a single solution.”

The study results are published in the Aug. 2 issue of *The New England Journal of Medicine*. The lead author is Dwight J. Rouse, M.D., of the University of Alabama at Birmingham. The study was conducted for the Maternal-Fetal Medicine Units Network of the National Institute of Child Health and Human Development, which provided grant funding. It took place at 14 sites across the United States, including UNC-Chapel Hill, WakeMed and the Wake County Health Department.

For the study, 655 healthy women with twin pregnancies and no prior preterm births received weekly injections of either 17-OHPC or placebo, starting at 16 to 20 weeks into their pregnancies and ending at 35 weeks. The results showed no meaningful difference between the 17-OHPC and placebo groups. Birth or miscarriage before 35 weeks gestation occurred in 41.5 percent of the 17-OHPC group and in 37.3 percent of the placebo group.

The researchers concluded that treatment with 17-OHPC did not reduce the rate of preterm birth in women with twins.

“Why 17-OHPC is effective in reducing the rate of preterm birth in women with a prior spontaneous preterm birth, but not in women carrying twins is a question that will be answered only when the mechanisms underlying preterm birth and the actions of 17-OHPC are better understood,” they wrote, adding that additional research is needed to see whether 17-OHPC is effective in other conditions in which the risk of preterm birth is increased.

Thorp said the same research network is currently working on two other 17-OHPC studies. One involves women with triplets while the other focuses on women with a short cervix. Both groups are considered to have an intermediate risk of preterm birth.

Another question for future research, Thorp said, is whether or not injections are the best method for administering 17-OHPC. It’s worth investigating whether other methods, such as daily vaginal suppositories, might be more effective, he said.

A commercial formulation of the drug, marketed under the name Gestiva, has been granted orphan drug status by the Food and Drug Administration and an application for full FDA approval is pending.

Source: University of North Carolina at Chapel Hill

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