# Vaginal Progesterone Lowers the Risk of Preterm Birth

Vaginal progesterone decreases the rate of premature birth according to the results of a phase 3 trial.

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May 7, 2018 – In women with a sonographic short cervix, vaginal progesterone was shown to reduce the risk of premature births in a phase 3 trial.

S.S. Hassan, MD, for the PREGNANT Trial, and colleagues reported their findings in the April 5, 2011 issue of *International Society of Ultrasound in Obstetrics and Gynecology*.

Micronized vaginal progesterone is a female hormone used to control cervical ripening. The vaginal progesterone is essential to women who are at increased risk of premature births and other neonatal complications due to a shortened cervix.

In this clinical trial, 465 women were randomly assigned to receive vaginal progesterone gel or placebo. Women who qualified were asymptomatic, carried a singleton fetus that measured between 19 and 23 weeks gestational age and had a cervical length of 10 to 20 mm measured by transvaginal ultrasound.

The vaginal progesterone was administered daily starting at 20 to 23 weeks and continued through 36 weeks gestation, rupture of membranes or delivery, whichever happened first. The primary endpoint was preterm delivery prior to 33 weeks gestation.

The women who received the vaginal progesterone gel in the second trimester had a 45% lower rate of preterm delivery before 33 weeks gestational age.

In the vaginal progesterone group, there was an 8.9% reduction in the rate of preterm births before 33 weeks compared with 16.1% in the placebo group. ($P = 0.02$) Significant reductions in preterm births before 28 weeks gestation (5.1% vs. 10.3%; $P = 0.04$) and 35 weeks gestation (14.5% vs. 23.3 %; $P = 0.02$) were also noted in the vaginal progesterone group compared with the placebo group. Respiratory distress syndrome (3.0% vs. 7.6%; $P = 0.03$) as well as any neonatal morbidity or mortality event (7.7% vs. 13.5%; $P = 0.04$) were also reduced with the use of vaginal progesterone gel.

Adverse events in the vaginal progesterone group were similar to those in the placebo group. Treatment related adverse events occurred in up to 2% of the women and included; vaginal pruritis, vaginal discharge, vaginal candidiasis and nausea.

“It is possible to assign an individualized risk for preterm delivery using sonographic cervical length and other maternal risk factors, such as, maternal age, ethnic group, BMI and previous cervical surgery. Among these factors sonographic cervical length is the most powerful predictor for preterm birth in the index pregnancy and is more informative than is a history of previous preterm birth.” J.M. O’Brien MD and colleagues noted in *Ultrasound Obstet Gynecol*.

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