

Experts in high-risk pregnancy respond to the published results of the PROLONG trial

25 October 2019

The Society for Maternal-Fetal (SMFM) released the following statement in response to the published results of "Progestin's Role in Optimizing Neonatal Gestation," more commonly referred to as the PROLONG trial, which was recently published in the *American Journal of Perinatology*.

"The PROLONG trial assessed the effectiveness of weekly injections of 17-alpha-hydroxyprogesterone caproate (17-OHPC) in reducing the incidence of recurrent [preterm birth](#) and neonatal morbidity. Between 2009 and 2018, this study enrolled more than 1,700 pregnant patients from nine countries and ultimately concluded that 17-OHPC does not decrease recurrent preterm [birth](#) or neonatal morbidity.

A previous large randomized control trial (Meis, 2003) also examined the effectiveness of 17-OHPC. Unlike PROLONG, this study found a 34% reduction in the incidence of recurrent preterm birth and significant reductions in several neonatal complications.

In comparing the conflicting results of the PROLONG and Meis [trials](#), one important consideration is the different populations studied. The Meis trial included a larger proportion of patients with additional risk factors for preterm birth. For example, 20% of the patients in the Meis trial reported smoking, compared to 8% in the PROLONG Trial. Other meaningful differences in the populations included:

- Race/Ethnicity
- Number of previous preterm births
- Marital status
- Reported substance use

SMFM has reviewed the results of the PROLONG trial and has released the SMFM Statement: Use of 17-alpha hydroxyprogesterone caproate for prevention of recurrent [preterm](#) birth, which recommends that obstetric care providers use an

individualized approach as they counsel patients regarding the use of 17-OHPC. It is reasonable for providers to continue to use 17-OHPC in the context of a shared decision-making model that includes consideration of risk level for recurrent PTB. Important factors to discuss include: uncertainly regarding the benefit, the lack of short-term safety concerns, the possibility of injection site pain, extra patient visits, and substantial costs.

Further, SMFM recommends additional research on 17-OHPC to identify populations in whom it is likely to be effective.

More information: 17-OHPC to Prevent Recurrent Preterm Birth in Singleton Gestations (PROLONG Study): A Multicenter, International, Randomized Double-Blind Trial, www.thieme-connect.com/product/1055/s-0039-3400227

Provided by Society for Maternal-Fetal Medicine

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