Does 17 Hydroxyprogesterone caproate (17-OHPC) supplementation prevent preterm labour?

What is known already?

In a population-based cohort of more than 18,000 mother-child dyads, in utero first trimester exposure to 17-OHPC was associated with cancer in offspring associatd with increased risk of any cancer (aHR 2.57, 95% CI 1.59, 4.15), and risk increased with number of injections (1–2 injections: aHR 1.80, 95% CI 1.12,2.90; ≥3 injections: aHR 3.07, 95% CI 1.34, 7.05). Exposure in the second or third trimester conferred an additional risk for male (aHR 2.59, 95% CI 1.07, 6.28) but not female (aHR 0.30, 0.04, 1.11) off-spring. Risk of colorectal (aHR 5.51, 95% CI 1.73, 17.59), prostate (aHR 5.10, 95% CI 1.24,21.00), and pediatric brain (aHR 34.72, 95% CI 7.29, 164.33) cancer was higher in offspring first exposed to 17-OHPC in the first1st trimester compared not exposed [Reference 1]

In 2003, Meis et al.(Reference 2) randomly assigned 459 patients with a documented history of spontaneous singleton preterm birth <37 completed weeks to weekly intramuscular injections of 17-OHPC or placebo beginning at 16 to 20 weeks of gestation and continuing until 36 weeks [Reference 2].

Meis et al in this study reported that this active prophylaxis significantly reduced the risk of preterm birth at all gestational age [Reference 2]. .

What is New?

Recently In 2020, a randomized placebo-controlled multicenter international trial (PROLONG) that assessed the safety and efficacy of 17-OHPC in over 1700 patients singleton gestation 2 trials, other randomized trials, and observational studies led the United States Food and Drug Administration (FDA) to conclude that use of 17-OHPC for prevention of recurrent preterm birth, is not supported by available evidence and withdrew its approval of the medication [Reference 3]

The American College of Obstetricians and Gynecologists (ACOG) concurred with this assessment [Reference 4].

Implications of the findings:

17-OHPC is not safe in first trimester and not shown to be effective for the indication for which they were approved and do not have benefits that outweigh their risks to patients.

References:

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