Protocol #45-Maternal Fetal Medicine, University of New Mexico

Prophylactic Supplemental Progesterone Treatment Protocol

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I. General

Preterm birth affects 12% of all births in the United States. It is the leading cause of perinatal morbidity and mortality worldwide. The prognosis of preterm neonates is related to the gestational age at birth. Approximately 25% of preterm births are secondary to maternal or fetal medical indications, however the majority of preterm deliveries are spontaneous due to preterm labor or preterm premature rupture of membranes. Clinical trials have shown a significant decrease in the rate of preterm delivery in women with a prior spontaneous preterm delivery with the administration of prophylactic supplemental progesterone treatment. Four-year follow-up trials found no adverse health outcomes of surviving children.

II. Requirements for Consideration of Supplemental Prophylactic Progesterone Treatment

1. Women with a singleton pregnancy and a prior preterm delivery secondary to spontaneous preterm labor or preterm premature rupture of membranes.
2. May consider progesterone supplementation in asymptomatic women with an incidentally identified short cervical length (less than 15mm) on endovaginal ultrasound exam.
3. No allergies to components of progesterone treatment or peanuts if using Prometrium.

III. Current Evidence Does Not Recommend Supplemental Prophylactic Progesterone Treatment in the Following circumstances

1. Women with a history of cervical insufficiency and a cerclage in place.
2. Women with multiple gestations.
3. Asymptomatic women with positive cervicovaginal fetal fibronectin result.
4. Use as a tocolytic agent or a therapeutic agent after tocolysis.

IV. Therapy

1. Progesterone supplementation for the prevention of recurrent preterm birth should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth due to spontaneous preterm labor or preterm premature rupture of membranes.
2. The ideal formulation/preparation, dosage, or route of progesterone supplementation is unknown.

3. We currently recommend the following regimens for prophylactic supplemental progesterone treatment to be initiated between 16-24 weeks until delivery or 36 weeks:
    a. 17 Alpha-Hydroxyprogesterone Caproate 250mg IM weekly.
    b. Micronized vaginal progesterone capsules 200mg QHS.

Prophylactic supplemental progesterone may be obtained from Highland Pharmacy, 717 Encino Place NE, Albuquerque, NM 87102. (505) 243-3777 or 1-800-305-0405.

CONSULTATION: Twenty-four hour consultation is available by calling the Maternal Fetal Medicine service at the University of New Mexico Hospital. 1-888-866-7257.

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O'Brien. Progesterone vaginal gel for the reduction of recurrent preterm birth: primary results from a randomized, double-blind, placebo-controlled trial. Ultrasound Ob/Gyn, 2007.

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