



17-Alpha Hydroxyprogesterone (17P) Protocol

RATIONALE

The rate of preterm birth in the United States has been rising over the last 15 years. Nationally, preterm birth affects 12% of all babies delivered in the United States or approximately 480,000 births. In the last decade, preterm birth has increased by 27% in the United States and accounts for 85% of all perinatal morbidity and mortality. Preterm birth is the leading cause of perinatal mortality among African Americans and the second leading cause among the overall American population. Although there is no test to accurately predict who will delivery preterm, women at greatest risk for preterm birth have a history of preterm delivery. The administration of 17 Alpha Hydroxyprogesterone has been proven to increase the gestational age at the time of delivery and decrease morbidity and mortality of some pregnant women with a prior preterm delivery.

Eligibility Criteria for 17 Alpha Hydroxyprogesterone

- ✓ History of spontaneous preterm birth (<37 weeks)
- ✓ Current singleton pregnancy
- ✓ Ideally, initiated treatment between 16 weeks 0/7 days and 20 weeks 0/7 days
- ✓ 17 Alpha Hydroxyprogesterone may be initiated as late as 26 weeks, 6/7 days-- although the data to support this is inconclusive

Pregnant women who should NOT be given 17 Alpha Hydroxyprogesterone with

- Known fetal anomaly
- Current or planned cervical cerclage
- Hypertension
- Seizure disorder
- Multi-fetal pregnancy (twins or greater)
- Short cervix and no prior preterm birth
- Previous medically indicated preterm birth
- History of preterm labor not associated with a term birth
- No history of preterm birth with preterm labor in current pregnancy

Treatment Protocol

- 17 Alpha Hydroxyprogesterone 250 mg, intramuscularly, every 7 days.
- Ideally, initiated treatment between 16 weeks 0/7 days and 20 weeks 0/7 days
- 17 Alpha Hydroxyprogesterone may be initiated as late as 26 weeks, 6 days--although the data to support this is inconclusive
- Terminate treatment at 36 weeks and 6/7 days or at birth, which ever comes first
- If the patient is experiencing signs and symptoms of preterm labor, continue to give her 17 Alpha Hydroxyprogesterone until she delivers or until 36 weeks, 6 days of pregnancy.
- Discontinuation prior to 36 weeks, 6 /7days of pregnancy can be associated with an increased risk of preterm birth

- Missed Doses- progesterone stays in the body for approximately 7 days. It is important that a woman receives a dose of 17 Alpha Hydroxyprogesterone every week. The suggested range of time in between injections is 5 to 9 days. If an injection is missed, be sure that the member receives the next dose as soon as possible and re-establish a new weekly schedule or she may stay on the same schedule. The patient will have no adverse effect from two (2) progesterone injections within 7 days. If a woman has difficulty keeping her weekly appointments, consider teaching her or a family member how to give the injection, arrange for a home health nurse to administer the injection when away from home, or arranging an alternate health care provider in the community such as retail store based walk-in clinic, urgent care center, general primary care provider, or home health agency. The patients' case manager can help arrange the details.

Precautions

- No proven effect on multiple gestations (twins or greater)
- 17 Alpha Hydroxyprogesterone is not to be used as a tocolytic or as an adjunct to tocolytic agents for patients in preterm labor or as a maintenance tocolytic by itself or with other tocolytic agents
- Although varying doses and regimens have been used in different studies, Health First Steps strongly urges the use of 17 Alpha Hydroxyprogesterone - 250 mg given intramuscularly weekly by a medical provider or home health nursing staff to ensure strict compliance.
- Side effects are very rare, but include soreness, swelling, itching and bruising.
- Check to make sure the patient is not allergic to the oils that the progesterone is mixed with. Progesterone can be compounded with different oils.
- 17 Alpha Hydroxyprogesterone is a bioidentical hormone produced in pregnancy and has been proven safe for mother and fetus. Currently, no adverse consequences have been found in either mother or child.

Additional Information

❖ Storing

The shelf life of 17 Alpha Hydroxyprogesterone is six months. 17 Alpha Hydroxyprogesterone is typically delivered in 5 ml vials. The medication can be kept at room temperature and does not need refrigeration. For best results, 17 Alpha Hydroxyprogesterone should be kept in a dry place away from direct heat and sunlight. Patients can transport vials to and from the office visit. If the medication looks cloudy it may have been stored for too long.

❖ Administering

- 17 Alpha Hydroxyprogesterone can be administered into the gluteus muscle, alternating sides each week. It may also be given in the anterior thigh.
- The weekly intramuscular dosage of 17 Alpha Hydroxyprogesterone is a 250mg (1 ml) injection, ideally given at the same time each week.
- The suggested range of time in between injections is 5 to 9 days- should it be necessary to plan around holidays or other delays.

- The 21-gauge 1½ inch needle needs to go all the way in before the medication is injected to make sure it is the muscle and not the subcutaneous fat.
- The 17 Alpha Hydroxyprogesterone medication is extremely thick. If the 17 Alpha Hydroxyprogesterone is injected subcutaneously instead of intramuscularly, this may cause a “knot” under the skin. The medication will get absorbed. If the site is painful, patients can take acetaminophen and/or place a warm (not hot) compress over the area, but this is usually not necessary.

Getting Patient Buy-in to enter the 17 Alpha Hydroxyprogesterone Program

It is essential that patients understand the importance of their commitment to maintaining the weekly injection regime and that 17 Alpha Hydroxyprogesterone does not guarantee a full-term pregnancy or a healthy baby. Patients must be counseled about how to reduce the risk of preterm birth and ways to recognize the signs of preterm labor. If a patient goes into preterm labor, other measures may be needed to delay birth and increase the probability of delivering a healthy baby. These might include tocolytics to stop contractions and steroids to help develop fetal lung maturity. Depending on the gestational age and other co-morbidities, a premature delivery is best performed at a facility that has a high-level Neonatal Intensive Care Unit (NICU).

Use of Progesterone to Reduce Preterm Birth. ACOG Committee Opinion No.419. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2008;112:963–5.

Websites

American College of Obstetricians and Gynecologists, District II- acogny.org

American College of Obstetricians and Gynecologists- acog.org

Center for Disease Control and Prevention-cdc.gov

Institute of Medicine- iom.edu

March of Dimes- marchofdimes.com