A Randomized Trial of 17 Alpha-Hydroxyprogesterone Caproate for Prevention of Preterm Birth in Multifetal Gestation

Objective

To determine whether 17 Alpha-Hydroxyprogesterone prevents preterm birth in multifetal pregnancies.

Conclusion

Treatment with 17 Alpha-Hydroxyprogesterone caproate did not reduce the rate of preterm birth in women with multigestations.

Clinical Centers

University of Pittsburgh, The University of Alabama at Birmingham, Wayne State University, Wake Forest University, Ohio State University, University of Texas Southwestern Medical Center, University of Utah, Drexel University, Brown University, Columbia University, Case Western Reserve University, University of Texas-Houston, University of North Carolina-Chapel Hill, Northwestern University

Type

Double masked randomized controlled trial

Major Eligibility Criteria

- Twin or triplet pregnancy
- Gestational age 16-20 weeks
- No previous fetal reduction except quads to triplets
- Absence of fetal anomalies

Groups

- Active: 1 ml IM with 250 mg of 17 a-hydroxyprogesterone caproate weekly
• Placebo: 1 ml IM inert oil weekly

**Sample Size**

Trial goals: 600 twin and 120 triplet pregnancies

**Management Protocols**

• Coded medication
  o Weekly injection (250mg) or placebo until 35 weeks

**Outcome Measures**

• Primary:
  o Preterm delivery (<35 weeks gestation)
• Secondary:
  o Randomization to delivery interval
  o Tocolytic therapy
  o Hospital admissions for preterm labor
  o Cerclage placement
  o Neonatal morbidity and mortality

**Timetable**

• Enrollment: Feb 2004 - Feb 2008
• Data Collection: Feb 2004 - Aug 2008
• Closeout/final analysis: Oct 2008 - Apr 2009