Objective

To establish whether administration of adjunctive antibiotics to women in preterm labor with intact membranes will decrease adverse perinatal outcome defined as mortality or composite morbidity.

Conclusion

The trial failed to support the routine use of antibiotic administration to women in preterm labor with intact membranes.

Clinical Centers

Magee Womens, Columbia, Tennessee, Thomas Jefferson U., LAC/USC, Yale

Major Eligibility Criteria

- Diagnosis of preterm labor (24-24 complete weeks)
- Less than 5 cm dilated
- Intact membranes

Groups

- Experimental = Tocolysis + steroids + antibiotics
- Placebo = Tocolysis + steroids + placebo

Sample Size

- Goal = 700 (350/group)

Outcome Measures

- Primary:
  Adverse perinatal outcome:
  - Mortality
  - Composite morbidity (RDS/BPD, IVH ≥ 3, NEC proven, sepsis proven, ROP ≥ 3)
- Secondary:
  Latency from randomization to delivery
  - Maternal infectious morbidity/placental infection
Long term infant morbidity (BPD/PIE/PDA/PVL/ROP)

**Timetable**

- Randomization (n=277): 12/89 - 7/91
- Follow-up: Thru - 1/92