MFMU Network Randomized Clinical Trial of Induction vs Expectant Management in Postterm Pregnancy

Objective

To establish whether immediate induction of labor in postterm pregnancies with cervices unfavorable for induction will decrease mortality or significant morbidity compared to expectant management with serial antepartum surveillance and selective induction.

Conclusion

The trial concluded that the incidence of the combined endpoint of maternal/perinatal death or perinatal morbidity in otherwise uncomplicated postterm pregnancies was very low and not significantly different between the two management regimens.

Clinical Centers

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

Major Eligibility Criteria

- EGA based on "good dates"
- Diagnosis of postterm pregnancy (at least 41 completed weeks, 287 days)
- No later than 301 days gestation
- Cervix unfavorable for induction
- Normal amniotic fluid volume and NST

Sample Size

- Goal = 2800 (700/year)

Groups

- Expectant = Serial antepartum surveillance
- Induction = Immediate induction of labor
  - PG-E2 = Prostaglandin-E2 gel
Placebo = Prostaglandin-E2 gel-placebo

Management Protocols

- Immediate induction:
  - PG-E2 or placebo (0.5 mg) within 24 hours
  - If no labor in 12 hours after gel, oxytocin administered
- Expectant management:
  - Weekly pelvic exams
  - Bi-weekly antepartum testing
  - Termination of expectant management, if:
    - Bishop score > 6
    - EFW > 4500 grams
    - Reduced fluid (ultrasound)
    - Equivocal cardiotocogram
    - Unequivocally positive stress test
    - > 307 days gestation

Outcome Measures

- Primary:
  - Mortality or composite morbidity:
    - Fetal or neonatal mortality
    - Maternal mortality
    - Composite morbidity: asphyxia, mechanical ventilation, Erb's palsy or other brachial plexus injury
- Secondary:
  - Maternal outcomes
  - Fetal outcomes

Timetable

- Randomization (n=440): 12/87 - 6/89
- Follow-up: Thru - 11/89