A Randomized Clinical Trial of Fetal Pulse Oximetry

Objective

To test the hypothesis that fetal pulse oximetry reduces the risk of cesarean delivery

Conclusion

The results concluded that knowledge of fetal oxygen saturation is not associated with a reduction in the rate of cesarean delivery.

Clinical Centers

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Major Eligibility Criteria

- 36° gestation
- Singleton pregnancy
- Nulliparous
- Cephalic presentation
- 2-5 cm dilated with ruptured membranes
- Informed consent

Design Type

Randomized clinical trial

Sample Size

- Goal = 10,000 patients (5,000 per group)

Management Protocols

- Standard fetal heart rate monitor
- Interpretation of oximetry reading
- Labor management at physician’s discretion

Outcome Measures

- Primary:
- Cesarean delivery (any indication)
  - Secondary:
    - Cesarean delivery for non reassuring fetal heart rate
    - Cesarean delivery for dystocia
    - Fetal vulnerability index (stillbirth, neonatal death, 5-min Apgar < 3, seizures, cord pH ≤ 7, intubation, intubation, NICU admission ≥ 24 hours)
    - Other neonatal morbidity

**Timetable**

- Training phase: 07/2001-02/2002 (7 months)
- Randomization: 02/2002-02/2004 (2 years)
- Data Collection: 02/2002 - 07/2004
- Closeout/Final Analysis: 07/2004-01/2005