A Randomized Clinical Trial of Treatment for Mild Gestational Diabetes Mellitus

Objective

To test the hypothesis that daily self blood glucose monitoring and diet therapy administered to women at 24-30 weeks gestation reduces the risk of large for gestational age infants.

Conclusion

Treatment of mild GDM lowers the risk for fetal overgrowth, shoulder dystocia, and cesarean delivery.

Clinical Centers

The University of Pittsburgh Magee Womens Hospital, The University of Alabama-Birmingham, Wayne State University, Wake Forest University, Ohio State University, The University of Texas Southwestern Medical Center, The University of Utah, Drexel University Hill, Brown University Women & Infants Hospital, Columbia University, Case Western Reserve University Metro Health, The University of Texas-Houston, University of North Carolina Chapel Hill, Northwestern University Prentice Womens Hospital

Major Eligibility Criteria

- Gestational age at enrollment 24 - 31 weeks
- GLT ≥ 135 mg/dl, OGTT positive (I, IIA)
- GLT ≥ 135 mg/dl, OGTT normal (IIB)
- GLT < 120 mg/dl, OGTT N/A (III)
- Informed consent

Design Type

Randomized Clinical Trial

Sample Size

- Trial goal = 950 (475/group I and IIA)
- Observational goal = 1,425 (950 IIB, 475 III)

Management Protocols

Group 1
• Daily blood glucose levels
• Nutritional counseling
• Insulin therapy may be prescribed if > half fasting levels > 95 mg/dl or postprandial glucose >120

**Group IIA**

• None

**Group IIB, III**

• None (observational)

**Outcome Measures**

• Primary:
  - Composite neonatal morbidity (hypoglycemia, heperinsulinemia, hyperbilirubinemia, birth trauma) death or stillbirth
• Secondary:
  - Large for gestational age
  - Macrosomia
  - Delivery route
  - Neonatal fat mass
  - Neonatal morbidity and mortality

**Timetable**

- Randomization/Enrollment: 06/2002-02/2005
- Data Collection: 06/2002-08/2005