TOPS

A Randomized Trial of Pessary in Singleton Pregnancies with a Short Cervix

Objective: To determine whether the Arabin pessary reduces the risk of preterm birth in women with a singleton pregnancy and a short cervix.

Project Status: Currently recruiting

Clinical Centers: All current centers

Design Type: Unmasked randomized clinical trial

Major Eligibility Criteria:

- Singleton gestation
- Gestational age 16^0 to 23^6 weeks
- Transvaginal cervical length ≤ 20.0 mm measured by a trained sonographer less than 10 days prior to randomization

Groups:

- Usual care (may include vaginal progesterone)
- Arabin pessary + Usual care

Sample Size: 850

Scheduled Evaluations / Data Collection:

Pre-Randomization:

- Transvaginal cervical length measurement by a trained sonographer

Randomization

- Vaginal sample, vaginal Gram stain and vaginal pH
- Pregnancy, exposure, and medical history

Post-randomization:

- Phone call to assess patient symptoms and compliance (pessary group) within one week of randomization
- Monthly study visits to assess symptoms and compliance (pessary group)
- Vaginal sample, vaginal Gram stain and vaginal pH collected between 26 and 30 weeks gestation
- Pessary group: Patient questionnaire 8 weeks after randomization and again at 37 weeks

Delivery:

- Delivery and neonatal data

Management Protocol:

Both groups:

- Vaginal progesterone per usual care

Pessary Group:

- Placement management from randomization to < 37 weeks gestation

Outcome Measures:

Primary:

- Delivery or fetal loss prior to 37 weeks

Secondary:

- Interval from randomization to delivery or fetal demise
- Gestational age at delivery
- Neonatal morbidity and mortality