Vaginal Pessary versus Expectant Management for the prevention of Delivery Prior to 36 weeks in Women with Placenta Previa (N=140)

Objective of the Research:
Comparing the role of vaginal pessary versus expectant management in women with placenta previa between 22w0d and 32w0d of gestation in prolonging gestation until ≥36 weeks. Secondary outcomes will assess duration of antepartum admission, total blood loss, gestational age at delivery, type of cesarean delivery, and composite neonatal outcome.

Inclusion Criteria (at time of randomization):
1. Participant 18 years or older
2. Gestational age between 22w0d and 32w0d, inclusive
3. Singleton Pregnancy
4. Complete Previa (≥10mm over internal os)
5. Intact Membranes
6. No allergies to material in cervical pessary
7. Plan to deliver at PI’s hospital
8. Informed consent obtained, signed and witnessed

Exclusion Criteria (at time of randomization)
1. Any contraindication to expectant management, including:
   a) Active preterm labor
   b) Nonreassuring fetal heart rate tracing
   c) Intrauterine fetal death
   d) Active bleeding (may be enrolled if no active bleeding >24 hours)
   e) Ruptured membranes
2. Any fetal condition likely to cause serious neonatal morbidity independent of gestational age, including:
   a) Malformation likely to require surgery
   b) Malformation involving vital organs
   c) Fetal viral infection
   d) Hydrops fetalis
3. Known uterine anomaly
4. Cervical cerclage present at time of enrollment

Principal Interventions:
1. Following enrollment, the participant will be randomized to the trial comparing the role of vaginal pessary versus expectant management in women with placenta previa between 22w0d and 32w0d of gestation.

Study Procedures:
1. Screen potential subjects for eligibility
2. Eligible participant gives informed consent & are enrolled
3. Randomized, assignment to treatment group once Placenta Previa (≥10mm beyond internal cervical os) is documented by ultrasound (abdominal or endovaginal)
   - Cervical Pessary- about 50%
   - Expectant management- about 50%

Patients assigned to receive a cervical pessary will be evaluated and fitted for a pessary by the physician within 3-4 days of randomization unless exclusion criteria develop. Strong precautions will be given to return to hospital if there is abnormal discharge, bleeding or pain. The patient will be given a card describing her enrollment in the study along with her precautions.

4. Follow-up US measurements of placenta previa and cervical length measurement will be performed at or before 32 weeks gestation as determined by the managing physician. If the patient no longer has a placenta previa she will be withdrawn from active participation in the study, the pessary removed if applicable, but data on her outcome will be recorded and reported to the trial.
5. The pessary will be removed at no earlier than 36w0d of gestation or may be removed earlier for the indications listed:
   a. uncontrolled hemorrhage. If the pt remains undelivered and the bleeding ceases, the pessary may be replaced within 24-48hrs
   b. Imminent preterm delivery
   c. PPROM at >34w0d
   d. Confirmed ROM. Pessary removal will be at the discretion of the MD
   e. s/s of uterine infection confirmed by amniocentesis
   f. IUFD
   g. Placenta previa no longer present as confirmed by u/s
   h. Patient request

All subsequent management will be at the discretion of the managing clinicians, with the exception that no elective deliveries will occur <36w0d gestation.