Cerclage Placement for the Prevention of Preterm Birth in Women with Placenta Previa (N=140)

Objective of the Research:
To compare the role of cervical cerclage versus expectant management in women with complete placenta previa (≥ 10mm over internal os) presenting with shortened cervical length (≥ 10mm and ≤ 30mm) between 18w0d and 26w0d of gestation.

Inclusion Criteria (at time of enrollment & randomization):
1. Singleton pregnancy, ≥ 18yrs old
2. GA 18w0d to 26w0d inclusive @ time of enrollment
3. Documentation of complete placenta previa (≥ 10mm over internal os)
4. Agrees to participate in trial and signs/date an informed consent form

Exclusion Criteria (at time of enrollment & randomization)
1. Any contraindication to expectant management (i.e. active labor, NRFHR, IUFD, uncontrolled hemorrhage)
2. Any fetal condition likely to cause serious neonatal morbidity independent of GA (e.g. hydrops, fetal viral infections, fetal malformations likely to need surgery like hydrocephalus, neural tube defects, cardiac defects, abdominal wall defects)
3. Known uterine anomaly at time of enrollment
4. A history of two or more prior cesarean deliveries
5. Suspected placenta accreta, increta or percreta on US at enrollment
6. Cervical cerclage present at time of enrollment

Principal Interventions:
1. Following enrollment, the participant will be expectantly managed and randomized to one of two treatment group if cervix shortens to ≥ 10mm and ≤ 30mm and she is between 18w0d & 26w0d of gestation:
   a. Prompt placement of a cervical cerclage
   b. Expectant management

Study Procedures:
1. Verify eligibility criteria
2. For women with risk factors identified, consent obtained
3. Progress note written discussing the informed consent process
4. Complete Enrollment & Screening Logs
5. Participants who do not shorten their cervix or who develop uncontrolled bleeding will **NOT be RANDOMIZED** and will only be used for descriptive purposes.
6. The enrolled participant **will ONLY be RANDOMIZED** if her cervical length measurement fall between ≥ 10mm and ≤ 30mm and the participant is between 18w0d and 26w0d of gestation.
7. Randomization will be done by calling an OBX CREQ staff (24hr/7days) 714-356-7328 or 602-741-1658
8. For those randomized and assigned to Cerclage Arm:
   a. Hospital admission for 24-72 hours and a McDonalds cerclage is to be placed within 72 hours of randomization
   b. Tocolytics may be administered at the time of cerclage placement
   c. F/U cervical length measurement done within 24 to 72 hours following cerclage placement
   d. Timing of removal will be no earlier than 36w0d unless indicated (e.g. uncontrolled hemorrhage, imminent PTD, PROM > 34wks or S/S of infection confirmed by amniocentesis)
9. Management common to all randomized patients, regardless of group assignment (Cerclage vs. Expectant Management)
   a. Collect a fFN sample @ randomization and with each transvaginal cervical length measurement until 34wks or delivery.
   b. Standard management for placenta previa
   c. Hospital admission for vaginal bleeding/hemorrhage
   d. Antenatal corticosteroids ≥ 24w0d of gestation
   e. Tocolytic therapy per physician’s discretion
   f. Magnesium sulfate for neuroprotection
   g. Fetal Heart Rate Monitoring
   h. Avoidance of digital examinations of the cervix
   i. Elective delivery no earlier than 36w0d gestation unless indicated (uncontrolled hemorrhage, imminent delivery, PROM > 34 wks, worsening maternal or fetal condition)