Induction in Nulliparous Women at 39 Weeks to Prevent Adverse Outcomes: A Randomized Controlled Trial

Objective: To determine whether elective induction of labor in nulliparous women at 39 weeks improves adverse perinatal/neonatal outcome compared with expectant management .

Project Status: Currently recruiting

Clinical Centers: UAB, Ohio State, UTSW, Utah, Brown, Columbia, Case Western, UT-Houston, UNC, Northwestern, UTMB-Galveston, Colorado, Duke, Stanford

Design Type: Unmasked randomized clinical trial stratified by clinical center

Major Eligibility Criteria:

- Singleton gestation
- Gestational age 38^0 to 38^6 weeks
- Nulliparous

Groups:

- Induction of labor at 39 weeks
- Expectant management with induction by 42 weeks, if undelivered

Sample Size: 6000

Scheduled Evaluations / Data Collection:

Randomization:

- Gestational age estimation
- Digital cervical exam; Bishop score
- Pregnancy, exposure and medical history

Post-randomization:

- Weekly visit with provider (expectant management group)

Delivery:

- Patient-centered outcomes questionnaire
- Delivery and neonatal data

Postpartum:

- Patient-centered outcomes questionnaire

Management Protocol:

Induction Group:

- Induction via oxytocin at 39^0-39^4 weeks
- If unfavorable cervix (modified Bishop score < 5) start with cervical ripening

Expectant Management Group:

- Continue pregnancy until at least 40^5 weeks (unless indication for delivery)
- Start antepartum fetal testing no later than 41^6
- Induction via oxytocin by 42^2 weeks
- If unfavorable cervix (modified Bishop score < 5) start with cervical ripening

Outcome Measures:

Primary:

- Neonatal adverse outcome/fetal death

Major Secondary:

- Cesarean delivery
- Maternal adverse outcomes
- Patient-centered outcomes
- Utilization of medical resources

Timetable:

- Enrollment: October 2013 to September 2016
- Data Collection: October 2013 to November 2016
- Closeout: December 2016 to March 2017