**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 to 38 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 39⁰-39⁴ weeks
  - If unfavorable cervix (modified Bishop score < 5) start with cervical ripening

Expectant Management Group:
  - Continue pregnancy until at least 40⁵ weeks (unless indication for delivery)
  - Start antepartum fetal testing no later than 41⁶
  - Induction via oxytocin by 42² 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