# Aspirin Supplementation for Pregnancy Indicated Risk Reduction In Nulliparas (ASPIRIN)

**Summary:**
A project in collaboration with Columbia University, with funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), USA

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## ABSTRACT

**Background:**
Preterm birth (PTB) remains the leading cause of neonatal mortality and long term disability throughout the world. Though complex in its origins, a growing body of evidence suggests that first trimester administration of low dose aspirin (LDA) holds promise to reduce the rate of PTB substantially.

**Hypothesis:**
First trimester administration of aspirin will reduce the risk of preterm birth.

**Study Design Type:**
Prospective randomized, placebo-controlled, double-blinded multicenter clinical trial. Trial will be individually randomized with one-to-one ratio (intervention/control)

**Population:**
Nulliparous women between the ages of 18 and 40, with a singleton pregnancy between 6 0/7 weeks and 13 6/7 weeks gestational age (GA) confirmed by ultrasound prior to enrollment, no more than two previous first trimester pregnancy losses, and no contraindications to aspirin. Minors who are ≥ 14 years of age may be enrolled if permitted by the country's ethical guidelines.

**Intervention:**
Daily administration of low dose (81 mg) aspirin, initiated between 6 0/7 weeks and 13 6/7 weeks GA and continued to 36 0/7 weeks GA, compared to an identical appearing placebo. Compliance and outcomes will be assessed biweekly.

**Outcomes**
***Primary:*** To determine whether daily LDA initiated between 6 0/7 -13 6/7 weeks GA and continued to 36 0/7 weeks GA reduces the risk of PTB (birth prior to 37 0/7 weeks GA).
***Secondary:*** of interest are the rate of preeclampsia/eclampsia, small for gestational age (SGA), and perinatal mortality.