Using Placental Pathology to Prevent Recurrent Adverse Pregnancy Outcomes: A Pilot Project

NCT06004674

Status	RECRUITING
Phase	Phase 2
Sponsor	Endeavor Health
Enrollment	20 participants

Plain Language Summary

This pilot study is testing whether a blood-thinning medication (enoxaparin/low molecular weight heparin) can help prevent complications in pregnant women who had a bad pregnancy outcome previously — such as premature birth, preeclampsia, or stillbirth — and whose placenta showed signs of poor blood flow.

You may be eligible if:
- You had a prior pregnancy complication (preterm birth, preeclampsia with severe features, low-birth-weight baby, or stillbirth)
- Your previous placenta showed signs of poor blood supply (maternal vascular malperfusion)
- You are currently pregnant with a single baby at less than 17 weeks

You may NOT be eligible if:
- You are already planned to take blood thinners in this pregnancy
- Your baby has a known major birth defect
- You are allergic to heparin or pork products, or have had a reaction to enoxaparin
- You have chronic kidney disease, chronic liver disease, a low platelet count, or a mechanical heart valve

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- Eligibility Criteria:
- Inclusion (must meet all three criteria):
- Subjects with a prior adverse outcome in a prior pregnancy. Adverse outcome is defined as prior singleton preterm birth (\< 37 weeks), SGA infant (defined as birthweight \< 10th percentile), preeclampsia with severe features, or stillbirth (fetal demise after 20 weeks gestation), as certified by an obstetrician
- Patients with maternal vascular malperfusion on pathology from pregnancy with prior adverse pregnancy outcome, as certified by a perinatal placental pathologist
- Current singleton pregnancy at \<16 6/7 weeks gestational age.

Exclusion (6)

- Anticoagulation planned for current pregnancy (including warfarin, enoxaparin, heparin)
- Known major fetal anomaly
- Contraindication to enoxaparin: Specifically active major bleeding, known thrombocytopenia (platelets \<100), hypersensitivity to enoxaparin sodium, hypersensitivity to heparin or pork products, hypersensitivity to benzyl alcohol
- Chronic kidney disease with eGFR\< 60
- Known chronic liver disease with baseline AST/ALT \> 3 x upper limit of normal

... and 1 more (see full listing online)

https://clinicaltrials.gov/study/NCT06004674

Locations (1 total)

NorthShore University HealthSystem, Evanston, Illinois, United States