IMPACT Study: IMProve Pregnancy in APS With Certolizumab Therapy

NCT03152058

Status	RECRUITING
Phase	Phase 2
Sponsor	David Ware Branch
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (6)

- Pregnant as defined by positive test for elevated ß-HCG and having a live, appropriate sized embryo by ultrasound, but \<8 weeks gestation;
- Antiphospholipid syndrome (APS);
- Positive for LAC on two or more occasions greater than 12 weeks apart within the previous 18 months. If a candidate for the study is newly diagnosed (\<12 weeks) with APS, meets clinical criteria for APS and has one positive LAC confirmed by review of the medical record, she may be consented and screened. At baseline, LAC will be measured at the study core lab and she will be enrolled if it is found to be positive. The LAC measurement will be repeated 12 weeks after the initial determination and, if positive, she will remain in the study.
- Age 18-40 (+364 days) years of age and able to give informed consent
- Laboratory hematocrit \>26% at time of screening.

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

Exclusion (20)

- Hypertension (BP \>140/90) present at screening;
- Multifetal gestation;
- Type 1 or Type 2 diabetes antedating pregnancy;
- SLE patients requiring prednisone \>10 mg/day;
- Platelet count \<100,000 per microliter;

... and 15 more (see full listing online)

Locations (3 total)

Hospital for Special Surgery, New York, New York, United States
University of Utah, Salt Lake City, Utah, United States
TRIO Advancing Reproductive Care, Toronto, Ontario, Canada

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.