

A Research Study to See How Safe is Eptacog Alfa When Used to Stop Heavy Bleeding in Women After Giving Birth in India

NCT07157423

Status	RECRUITING
Phase	Phase 4
Sponsor	Novo Nordisk A/S
Enrollment	64 participants

Key Eligibility Criteria

Inclusion (2)

- Informed consent obtained before any study-related activities. Study-related activities are any procedures that are carried out as part of the study, including activities to determine suitability for the study except for blood loss estimation post-partum
- Adult women aged greater than or equal to (e) 18 years at the time of signing the informed consent and who deliver after 27 weeks diagnosed with severe postpartum haemorrhage (PPH) who fail to respond to uterotonics

Exclusion (8)

- Previous participation in this study. Participation is defined as having given informed consent in this study
- Mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation
- Patient with a history of thromboembolism
- Patient with a history of bleeding disorders
- Patient with a history of or ongoing disseminated intravascular coagulation (DIC); haemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome, thrombotic thrombocytopenic purpura (TTP), pre-eclampsia or other severe complication of childbirth apart from severe PPH

... and 3 more (see full listing online)

Locations (8 total)

KLE Belgum, Belagavi, Karnataka, India
Calicut Medical College, Kozhikode, Kerala, India
Calicut Medical College, Kozhikode, Kerala, India
... and 5 more locations