Safety and Effectiveness of the KOKO Device to Treat Primary Abnormal Postpartum Uterine Bleeding or Hemorrhage

NCT06452355

Status	RECRUITING
Phase	Not Applicable
Sponsor	KOKO Medical Inc.
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (5)

- Adult Female, 18 years of age or older at time of consent.
- Subject is able to understand and provide informed consent to participate in the study.
- Diagnosis of abnormal postpartum uterine bleeding (500 - 999 ml for vaginal birth) or postpartum hemorrhage (1000 - 1500 ml for vaginal or Cesarean birth) with suspected atony within 24 hours after vaginal or cesarean birth.
- EBL, to be determined when investigator is ready to have the KOKO packaging opened: Vaginal birth: 500 - 1500 ml EBL or Cesarean birth: 1000 - 1500 ml EBL.
- Failed first - line intervention of uterotonics and uterine massage/bimanual uterine massage to stop bleeding. Note: Uterotonic administration may continue concomitant with and post KOKO use.

Exclusion (20)

- EBL \>1500ml, to be determined when investigator is ready to have the KOKO packaging opened.
- Delivery at a gestational age \< 34 weeks or, if multiples, uterus is judged \<34 weeks size.
- For cesarean births: Cervix \< 2.5 cm dilated before use of KOKO.
- Abnormal postpartum uterine bleeding or hemorrhage that the investigator determines to require more aggressive treatment, including any of the following:
- hysterectomy;

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

Locations (19 total)

University of Alabama, Birmingham, Alabama, United States
Christiana Care, Newark, Delaware, United States
University of Miami, Miami, Florida, United States
... and 16 more locations