EVE TRIAL , ALMA SYSTAM

NCT06646653

Status	RECRUITING
Phase	Phase 3
Sponsor	ResQ Medical Ltd
Enrollment	50 participants

Plain Language Summary

This study is testing the Alma System, a device designed to control severe postpartum hemorrhage (heavy bleeding after childbirth) caused by a uterus that fails to contract properly — a condition called uterine atony — after first-line medications have not stopped the bleeding.

You may be eligible if...
- You are 18 years or older
- You gave birth vaginally and lost 500 mL or more of blood, OR had a cesarean section and lost 1,000 mL or more
- Your uterus has not contracted for at least 10 minutes after delivery of the placenta
- Standard first-line treatments (uterotonic medications and uterine massage) have not worked

You may NOT be eligible if...
- Your bleeding is caused by something other than uterine atony (e.g., retained placenta, lacerations, uterine rupture)
- You delivered at less than 34 weeks of pregnancy
- You have already lost more than 1,000 mL (vaginal birth) or 2,000 mL (cesarean) of blood
- You have abnormal blood clotting tests
- The investigator determines more aggressive treatments (such as hysterectomy) are needed immediately

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

Key Eligibility Criteria

Inclusion (6)

- • Adult Female, 18 years of age or older at time of consent.
- • Able to understand and provide informed consent to participate in the study.
- • Diagnosis of abnormal postpartum uterine bleeding or hemorrhage with suspected atony within 24 hours after vaginal or c-section delivery.
- • EBL, determined when investigator is ready to have the Alma peel pack opened:
- • Vaginal delivery: 500 - 1500 ml EBL or C-section delivery 1000 - 1500 ml EBL

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

Exclusion (20)

- • EBL \>1500ml, to be determined when investigator is ready to have the Alma peel pack opened.
- • Delivery at a gestational age \< 34 weeks.
- • For Cesarean-sections birth: Cervix \< 3 cm dilated before use of Alma.
- • PPH that the investigator determines to require more aggressive treatment, including any of the following:
- • hysterectomy;

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

Locations (2 total)

https://clinicaltrials.gov/study/NCT06646653

- Maimonides Medical Center | Brooklyn, New York Hospital, Brooklyn, New York, United States

Shaare Zedek Medical Center, Jerusalem, Israel