A Study to Compare the Efficacy and Safety of TachoSil and Surgicel Original as an Adjunct to Control Mild to Moderate Soft Tissue Bleeding During Surgery

NCT06664775

Status	RECRUITING
Phase	Phase 3
Sponsor	Corza Medical GmbH
Enrollment	116 participants

Key Eligibility Criteria

Inclusion (5)

- Elective open abdominal, retroperitoneal, pelvic, or thoracic surgery. Elective transplant surgery except for liver or heart transplants is included.
- The participant has a need for secondary hemostatic study intervention at the TBS with mild to moderate bleeding Grade 1 and Grade 2 according to the VIBe Scale.
- Presence of an appropriate mild to moderate bleeding soft tissue TBS identified intra-operatively by the surgeon.
- The TBS size \< 21 cm2/3.3 in2.
- Ability to firmly press study intervention at TBS until 3 minutes after randomization.

Exclusion (10)

- Participants undergoing cardiovascular, hepatic, and laparoscopic and robotic surgeries.
- Congenital or acquired disorders of coagulation.
- Diseases requiring constant use of any anticoagulant drugs that cannot be safely washed out prior to randomization.
- Screening Hemoglobin \< 9 mg/dL, platelets \< 75 × 103/µL, and/or international normalized ratio (INR) \> 1.5.
- Acute major bleeding during surgery.

... and 5 more (see full listing online)

Locations (9 total)

Torrance Memorial, Torrance, California, United States
St. Anthony Hospital, Lakewood, Colorado, United States
Georgetown University, Washington D.C., District of Columbia, United States
... and 6 more locations