

TISSEEL (Fibrin Sealant) for Vaginal Vault Haematoma

ACTRN12621000146897

Status	RECRUITING
Sponsor	Gold Coast Hospital and Health Service
Enrollment	400 participants

Plain Language Summary

After a hysterectomy (surgical removal of the uterus), a small blood collection can sometimes form at the top of the vagina where it was closed off — called a "vaginal vault haematoma." While often minor, this complication can lead to infection, pain, prolonged hospital stay, or even the need for additional procedures. Surgeons are looking for ways to reduce how often this happens.

This trial is testing TISSEEL, a fibrin sealant (a type of biological glue made from blood-clotting proteins) that is applied to the surgical site at the end of the operation to help stop minor bleeding. The study compares outcomes between women who receive TISSEEL and those who do not, measuring the rate of haematoma formation on ultrasound scan after surgery.

Women aged 18 or older who are having a total laparoscopic hysterectomy (keyhole removal of the uterus) for a non-cancerous condition at Gold Coast University Hospital under a specific gynaecologist are eligible. Women with previous cancer, known clotting disorders, or allergies to TISSEEL ingredients are excluded. After the operation, participants will receive a phone call questionnaire and a follow-up ultrasound scan to check for any haematoma.

Key Eligibility Criteria

Inclusion (4)

-) Females
-) 18 years old and over
-) Undergoing a Total Laparoscopic Hysterectomy for benign pathology at Gold Coast University Hospital
-) Operational consultant listed as Dr Walker

Exclusion (4)

-) Previous or concurrent diagnosis of malignancy
-) Known coagulopathy
-) Known allergy to TISSEEL excipients
-) Concurrent use of alternative haemostatic agents other than TISSEEL during operation

Locations (1 total)

QLD, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621000146897>

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 anzctr.org.au. Generated by ClinicalTrialsFinder.org.