Topical Gabapentin Amitriptyline and Lignocaine (ToGA) ointment trial for posthaemorrhoidectomy analgesia

ACTRN12616001477415

Status	RECRUITING
Sponsor	Monash Health
Enrollment	166 participants

Plain Language Summary

This study is testing whether a special cream containing three medicines — gabapentin, amitriptyline, and lignocaine — can reduce pain after haemorrhoid surgery (haemorrhoidectomy). After surgery, patients will use either the medicated cream or a plain cream (placebo) and record their pain levels in a diary. Researchers are also tracking how much extra pain medication patients need.

You may be eligible if:
- You are between 18 and 80 years old (male or female)
- You are scheduled for elective haemorrhoid surgery under general anaesthesia
- You have Grade III or IV haemorrhoids
- You are generally healthy enough for surgery (ASA physical status I–III)

You may NOT be eligible if:
- You have difficulty making decisions or cannot give informed consent
- You are not able to keep a pain diary
- You are allergic to gabapentin, amitriptyline, or lignocaine
- You have a history of drug or alcohol abuse or opioid dependence
- You are pregnant, a child, or have terminal organ failure

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

• Adult patients of any sex between age 18-80 years old, with American Society of Anesthesiologists (ASA) physical status I to III, who is scheduled for elective formal haemorrhoidectomy for grade III or IV haemorrhoids under general anaesthesia.

Exclusion (2)

• Patients with impaired decision-making ability, incapable to consent for procedure, perceived inability to complete pain diary, allergy to the Gabapentin, Amitriptyline, or Lignocaine, history of drug and alcohol abuse, opioid dependence, or do not have the capacity to weigh up potential risks and benefits of the trial will be excluded. Pregnant women, children or patients with disease states or terminal organ impairment will also be excluded from the study. Written and verbal informed consent will be obtained from all patients.

• If during post-operative follow-up, patients were found to have surgical site infection, they will be excluded from the final analysis of pain control. These patients will still be included in the secondary comparative analysis between the two randomised groups.

Locations (2 total)

Dandenong Hospital - Dandenong, VIC, Australia
Casey Hospital - Berwick, VIC, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616001477415