

Botulinum Toxin A in Abdominal Hernia Repair

ACTRN12624000701527

Status	RECRUITING
Phase	Phase 4
Sponsor	Dr Mary Ann Johnson
Enrollment	168 participants

Plain Language Summary

Large hernias in the abdominal wall — where internal organs push through a weakness or opening in the muscle — can be difficult to repair surgically because the abdominal muscles pull outward with considerable force, putting strain on the repair site. Botulinum Toxin A (BTA, commonly known as Botox) can temporarily relax these muscles for about three months, potentially making surgery easier and reducing the chance of the hernia coming back.

This double-blinded randomised trial will compare outcomes for 168 patients who receive either BTA injections or saline (placebo) injections into their abdominal muscles 4–6 weeks before hernia repair surgery. Researchers will assess how well the hernia closes during surgery, recovery speed, recurrence rates, and healthcare costs.

You may be eligible if you are 18 or older and have a large ventral hernia that requires surgical repair, as assessed at the relevant surgical clinic. People with myasthenia gravis, Eaton Lambert syndrome, a hernia defect greater than 14 cm wide, or an infection at the injection site are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Is greater than and equal to 18 years of ages at enrolment
- Has a large ventral hernia that requires surgical repair as determined by attendance of the Hepatobiliary and Upper Gastrointestinal Surgical Clinic
- Ability to understand study information in English
- Provide a signed and dated informed consent form

Exclusion (6)

- Emergency procedures
- Prisoners
- Hernia with defect greater than 14cm transversely or more than 50% loss of domain
- Known hypersensitivity to any ingredient in the formulation.
- Participants with myasthenia gravis or Eaton Lambert syndrome.

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

Locations (4 total)

St Vincent's Hospital (Melbourne) Ltd - Fitzroy, VIC, Australia
Epworth Eastern Hospital - Box Hill, VIC, Australia
Box Hill Hospital - Box Hill, VIC, Australia
... and 1 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000701527>

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