

# Amnion cell derivatives for fistulising perianal Crohn's disease

ACTRN12624000778583

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Status	RECRUITING
Sponsor	Monash Health
Enrollment	15 participants

## Plain Language Summary

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Perianal fistulas — abnormal tunnels that develop near the anus — are a particularly difficult-to-treat complication of Crohn's disease. They can cause ongoing pain, discharge, and significantly impact quality of life. Despite available medications and surgery, many people experience persistent or returning fistulas that are hard to heal.

This study is testing an innovative new approach using products derived from stem cells found in the placenta (amniotic epithelial cells). A previous Phase I study using these cells showed the treatment was safe and improved fistula healing in 8 out of 10 patients. This new study uses products secreted by those cells, which may have similar healing and anti-inflammatory effects. The treatment is injected directly into the fistula during an examination under anaesthesia.

You may be eligible if you are an adult with complex perianal Crohn's fistulas that have not responded to at least one previous treatment (antibiotics or immunotherapy), and your Crohn's disease is currently mild or inactive. You must not be pregnant and should not have a large abscess or active severe inflammation in the rectum.

## Key Eligibility Criteria

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### Inclusion (7)

- Adult participant
- Non-active or mildly active luminal Crohn's for over 6 months defined by a Crohn's Disease Activity Index (CDAI) less than 220
- Presence of complex perianal fistulas as classified by the American Gastroenterological Association (AGA)
- More than 1 of the following: high intersphincteric, high trans-sphincteric, extra-sphincteric, supra-sphincteric, more than 2 external openings or associated collections
- Fistulas with a maximum of 2 internal and 3 external openings
- ... and 2 more (see full listing online)

### Exclusion (6)

- Rectal or anal stenosis
- Active severe proctitis (presence of superficial or deep ulcers)
- Abscess or collection more than 2 cm size that were not properly drained
- Corticosteroid use within the previous 4 weeks
- Inability to tolerate or comply with trial requirements
- ... and 1 more (see full listing online)

## Locations (1 total)

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VIC, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000778583>

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