

A prospective, randomised study comparing the use of Actifuse (trademark) Advanced Bone Matrix (ABX) synthetic bone substitute with INFUSE (registered trademark) in patients requiring posterolateral instrumented lumbar fusion.

ACTRN12609000548235

Status	RECRUITING
Sponsor	ApaTech Ltd
Enrollment	100 participants

Plain Language Summary

This study is comparing two materials used in a type of lower back surgery called posterolateral lumbar fusion. When the discs in your lower back break down, they can cause back and leg pain. In some cases, surgery is needed to fuse the vertebrae (spine bones) together. During this procedure, a bone-like substance is placed to help the bones knit together. This trial tests whether a synthetic substitute called Actifuse ABX works as well as a product called INFUSE (which contains a bone-stimulating protein).

You may be eligible if:

- You have degenerative disc disease of the lower back causing back or leg pain
- Your imaging (X-ray, CT, or MRI) shows signs of disc or spinal joint damage
- Your Oswestry Back Disability Score is 30 or more
- You are between 18 and 80 years old

You may NOT be eligible if:

- You have had a previous failed spinal fusion at the same level
- You have a spinal infection, tumor, or trauma
- You need surgery at more than two spinal levels
- You have osteoporosis
- You are pregnant

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

Key Eligibility Criteria

Inclusion (9)

- Has degenerative disc disease of the lumbar spine as indicated by back pain of discogenic/degenerative origin, with or without leg pain, and has one or more of the following conditions as documented by plain X-rays, CT scan or Magnetic Resonance Imaging (MRI) scan:
 - a) Modic Changes.
 - b) High intensity changes in the annulus.
 - c) Loss of disc height
 - d) Decreased Hydration of the disc
- ... and 4 more (see full listing online)

Exclusion (1)

- Has had previous failed attempts at fusion surgery at the involved level(s). Has a diagnosis of spinal infection, tumour or trauma. Requires surgery at more than two (2) levels. Has osteoporosis (excluding osteopenia) as evidenced on plain X-rays, CT scans

<http://www.anzctr.org.au/Trial/Registration/TrialListing.aspx?ID=34113>

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.

Locations (1 total)

Australia