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 with interbody fusion

ACTRN12609000527268

Status	RECRUITING
Sponsor	ApaTech Ltd
Enrollment	100 participants

Plain Language Summary

This study is testing two different bone graft materials used during a type of spine surgery called lumbar fusion with interbody fusion. When the discs in your lower back wear down and cause back or leg pain, surgery is sometimes needed to fuse the vertebrae together. During this surgery, a bone-like material is placed to help the bones grow together. This trial compares a synthetic bone substitute called Actifuse ABX with a product called INFUSE to see which works better.

You may be eligible if:
- You have degenerative disc disease of the lower back causing back pain, with or without leg pain
- Your imaging scans (X-ray, CT, or MRI) show changes in your spine such as disc height loss, canal narrowing, or joint changes
- Your Oswestry Back Disability Score is 30 or higher (indicating significant disability)
- You are between 18 and 75 years old

You may NOT be eligible if:
- You have previously had a failed fusion surgery at the same level
- You have a spinal infection, tumor, or spinal trauma
- You need surgery at more than two spinal levels
- You have osteoporosis (not just osteopenia)
- 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 (5)

- 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 (or Dual X-ray Absorptometry (DEXA) scan in cases of doubt).

• Is pregnant.

Locations (1 total)

Netherlands