

A multi-center, prospective, randomised controlled trial comparing the efficacy and safety of PRODISC-C implant to anterior cervical discectomy and fusion (ACDF) surgery, in the treatment of symptomatic cervical disc disease (SCDD)

ACTRN12611000646943

Status	RECRUITING
Phase	Phase 4
Sponsor	Synthes Asia Pacific
Enrollment	300 participants

Plain Language Summary

This study compares a cervical disc replacement implant (called ProDisc-C) with the standard surgical treatment for neck disc disease (anterior cervical discectomy and fusion, or ACDF). When a disc in the neck wears out and presses on a nerve, it can cause neck pain, arm pain, and weakness. The new implant is designed to relieve pain while still allowing movement in the neck, unlike the fusion procedure that locks the vertebrae together.

You may be eligible if:

- You are between 18 and 65 years of age
- You have neck or arm pain caused by a diseased disc at a single level between C3 and C7 in your neck
- The problem has been confirmed on a scan (CT, MRI, or X-ray)
- Non-surgical treatments have not helped after about 6 weeks, or your symptoms are getting worse
- Your neck disability score is 30% or higher (moderate disability)

You may NOT be eligible if:

- More than one level of your neck requires treatment
- You have severe facet joint disease in the neck
- You have a known allergy to cobalt, chromium, molybdenum, titanium, or polyethylene
- You have osteoporosis or another metabolic bone disease
- You have insulin-dependent diabetes, a rheumatic disease, or an active infection
- You are pregnant

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

Key Eligibility Criteria

Inclusion (7)

- Subjects with symptomatic cervical disc disease (SCDD) in only one vertebral level between C3-C7 defined as:
 - Neck or arm (radicular) pain; and/or a functional / neurological deficit with at least one of the following conditions confirmed by imaging (Computed Tomography scans, Magnetic Resonance Imagings or X-rays)
 - Herniated nucleus pulposus
 - Spondylosis (defined by the presence of osteophytes)
 - Loss of disc height
- ... and 2 more (see full listing online)

Exclusion (25)

- More than one vertebral level requiring treatment (showing marked changes at a second level)
- <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12611000646943>
- Marked cervical instability on resting lateral or flexion/extension radiographs:

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- a.translation greater than 3 mm and/or
 - b.greater than 11 degrees of rotational difference to that of either adjacent level .
 - Radiographic confirmation of severe facet joint disease or degeneration.
- ... and 20 more (see full listing online)

Locations (5 total)

Seoul, Korea, Republic Of
Beijing, China
New Territories, Hong Kong
... and 2 more locations