A multi center, prospective, randomized controlled trial comparing cervical arthroplasty to anterior cervical discectomy and fusion (ACDF) for the treatment of cervical degenerative disc disease.

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The primary objective of this investigation is to evaluate the performance of the DISCOVER Artificial CervicalDisc in the treatment of cervical disc disease by measuring the function assessed via Neck Disability Index(NDI) and neurological function...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39490

Source
ToetsingOnline

Brief title
Discover Artificial cervical disc IDE

Condition

- Head and neck therapeutic procedures

Synonym
Cervical disc disease

Research involving

Human

Sponsors and support

Primary sponsor: Johnson & Johnson
Source(s) of monetary or material Support: DePuy Spine;Inc.

Intervention

Keyword: Cervical disc, Discover, IDE, Medical device

Outcome measures

Primary outcome

Primary endpoint:

The primary endpoint is patient success as determined by clinical outcome measures.

1)Clinical Success requires a minimum of 15-point improvement in NDI,

2) no new clinically significant permanent abnormalities in neurological function (i.e., motor strength, nerve root tension signs, sensory and reflex signs),

3) no subsequent secondary surgical interventions at the index level, and no device-related serious adverse events (SAE) from baseline through 24-months

Secondary outcome

Secundary study parameters/outcome of the study (if applicable):

Secondary endpoints:

• The change in pain relief assessed via Visual Analogue Scale (VAS) from pre-treatment for DISCOVER will be measured prior to discharge post op, 2 weeks, 3, 6, 12 and 24 months post op

and compared

with ACDF

• The change in Quality of Life assessed by SF-36 from pre-treatment for

DISCOVER will be measured at 12 and

24 months post op and compared with ACDF

• The change in function assessed by Neck Disability Index from pre-treatment

for DISCOVER will be

measured at 2 weeks, 3, 6, 12 and 24 months post op and compared with ACDF

• The change in Neurological function assessed by motor strength, nerve root

tension signs, sensory and

reflex signs from pre-treatment for DISOVER will be measured prior to

discharge, 2 weeks, 3, 6, 12 and 24 months post op and compared with ACDF

• The work status of the subject will be assessed from pre-treatment for

DISCOVER and measured at 2 weeks,

3, 6, 12 and 24 months post op and compared with ACDF

• The effect on sagittal angulation, measured by Radiographic Grade for

DISCOVER will be measured at pretreatment,

prior to discharge post op, 2 weeks, 3, 6, 12 and 24 months post op and

compared with ACDF

• The effect on adjacent level degeneration measured by Radiographic Grade for

DISCOVER will be measured

at pre-treatment and 24 months and compared with ACDF

• The effect on maintenance of disc height measured by Radiographic Grade for

DISCOVER will be measured

at pre-treatment, prior to discharge post op, 2 weeks, 3, 6, 12 and 24 months

and compared with ACDF

• The effect on foraminal height measured by Radiographic Grade for DISCOVER

will be measured at pretreatment,

12 and 24 months and compared with ACDF

• The effect on Cervical Range of Movement (CROM) measured by Radiographic

Grade for DISCOVER will be

measured at pre-treatment, 3, 6, 12 and 24 months and compared with ACDF

• The safety of the DISCOVER Artificial Cervical Disc by documenting the

incidence of device-related serious

adverse events and monitoring neurological function as measured by neurological

examination and compared with ACDF

• Implant survival for surgical revision at the level of intervention assessed

throughout 60 months of followup.

Study description

Background summary

Anterior cervical discectomy and fusion (ACDF) was initially described by
Robinson and Smith, and then by
Cloward in the late 1950's 1, 2. The ACDF procedure has gained increasing
popularity amongst neurosurgeons
and orthopaedic spine surgeons and is an established procedure for the surgical
treatment of cervical disc
herniation and spondylosis3. The ACDF procedure has a history of success with
regard to fusion, with success
rates at or above 90% 4-8 Even though ACDF has been the treatment of choice for
physicians treating
patients with cervical degenerative disc disease (DDD), there has been
increasing concern at the possible

acceleration of adjacent level degeneration, and loss of motion.
Based on reported short-term outcomes, maintaining or restoring motion at a diseased cervical joint appears
to be a viable option in terms of preventing or limiting adjacent level disc disease, and relieving pain and
radicular symptoms of those affected with this debilitating disease.

Study objective

The primary objective of this investigation is to evaluate the performance of the DISCOVER Artificial Cervical
Disc in the treatment of cervical disc disease by measuring the function assessed via Neck Disability Index
(NDI) and neurological function when compared to Anterior Cervical Discectomy and Fusion (ACDF).

Study design

A multi-centre, prospective, randomised, post marketing surveillance study. Subjects will either receive allograft bone with an anterior cervical plate and allograft (control group) or an artificial cervical disc (investigational
group).

Intervention

Subjects with cervical disease are currently treated with Anterior Cervical Decompression and Fusion (ACDF)
or cervical disc replacement. Cervical spinal fusion is a surgery that joins selected bones in the cervical spine
(neck). There are different methods of performing a cervical spinal fusion. The method for this research study
will use allograft bone (bone donated from another patient) that is placed in the space where the disc was, together with a plate fixed to the bone above and below the removed disc to join together the affected bones in the neck.
SLIM-Loc Anterior Cervical Plate is the name of the plate that is being used in the study.
The newer treatment that subjects may get by taking part in this research study is cervical arthroplasty using
the DISCOVERTM artificial cervical disc, this is a disc replacement treatment, which means the surgeon will

remove the affected disc and insert the artificial disc. Both operations will be performed through an incision on the front of the neck.

Study burden and risks

Any surgical procedure poses a potential risk and the procedures undertaken as part of this clinical
investigation are no exception. There are known risks associated with the method of anaesthesia (general,
epidural, local). In addition to these there are risks associated with a surgical procedure that involves a
device. A complication may require revision surgery. Very rarely a complication may prove fatal. Risks that are associated with the use of the Artificial Cervical Disc are expected to be similar to risks associated with ACDF. An extensive literature review was performed on the use of ACDF in subjects with DDD.
Potential risks include, but are not limited to, procedure-related complications that are intrinsic to the anterior
cervical surgical approach (See section E9 on this form).

Contacts

Public
Johnson & Johnson

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Scientific
Johnson & Johnson

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Key Inclusion Criteria:;- Objective evidence of cervical disc disease in 1 vertebral level between C3-C7 defined as
(a) shoulder and/or arm pain in a documented radicular distribution resulting from herniated disc or bony osteophytes or
(b)myeloradiculopathy resulting from mild spinal cord compression and nerve root impingement
- Unresponsiveness to documented non-surgical management for greater than or equal to 6 weeks and/or presentation with progressive symptoms of nerve root or spinal cord compression in the face of continued non-surgical management
- Moderate Neck Disability Index (NDI) score
- Able to give informed consent for study participation
- Able and willing to return for all follow-up visits

Exclusion criteria

Key Exclusion Criteria:;- Significant cervical degenerative disc disease
- Prior fusion procedure at any level(s) (C1-T1)
- Marked cervical instability on lateral or flexion/extension radiographs
- Presence of systemic infection or infection at the surgical site
- Diagnosis of a condition, or requires postoperative medication(s), which may interfere with bony/soft tissue healing
- History of alcohol and/or drug abuse
- Any known allergy to a metal alloy or polyethylene
- Morbid obesity
- Any significant general illness (e.g., metastatic cancer, HIV)

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2010
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	DISCOVER Artificial Cervical Disc
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-06-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-10-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-06-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-05-2013
Application type:	Amendment

Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00432159
CCMO	NL27720.008.09