A MULTI-CENTRE, PROSPECTIVE, POST MARKETING SURVEILLANCE STUDY INVESTIGATING THE PERFORMANCE OF CERVICAL ARTHROPLASTY FOR THE TREATMENT OF CERVICAL DEGENERATIVE DISC DISEASE (DDD)

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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...

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

Summary

ID

NL-OMON33921

Source
ToetsingOnline

Brief title
DISCOVER Artificial Cervical Disc

Condition

- Head and neck therapeutic procedures

Synonym
Cervical degenerative disc disease

Research involving

Human

Sponsors and support

Primary sponsor: DePuy International Ltd.
Source(s) of monetary or material Support: DePuy International Ltd.

Intervention

Keyword: cervical disc, discover, medical device, post-marketing surveillance

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

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, 6 weeks, 6, 12, 24, 36, 48, and 60 months post op

* The change in Quality of Life assessed by SF-36 from pre-treatment for DISCOVER will be measured at 12, 24, 36, 48, and 60 months post op

* The change in function assessed by Neck Disability Index from pre-treatment for DISCOVER will be measured at 6 weeks, 6, 12, 24, 36, 48, and 60 months post op

* 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, 6 weeks, 6, 12, 24, 36, 48, and 60 months post op

* The work status of the subject will be assessed from pre-treatment for DISCOVER and measured at 6 weeks, 6, 12, 24, 36, 48, and 60 months post

* The effect on sagittal angulation, measured by Radiographic Grade for DISCOVER will be measured at pre-treatment, prior to discharge post op, 6 weeks, 6, 12, 24, 36, 48, and 60 months post op

* The effect on adjacent level degeneration measured by Radiographic Grade for DISCOVER will be measured at pre-treatment 24, 36, 48, and 60 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, 6 weeks, 6, 12, 24, 36, 48, and 60 months

* The effect on foraminal height measured by Radiographic Grade from

pre-treatment for DISCOVER will be measured post-operatively 6 weeks, 12, 24, 36, 48, and 60 months

* The effect on Cervical Range of Movement (CROM) measured by Radiographic Grade from pre-treatment for DISCOVER will be measured at 6 weeks, 6, 12, 24, 36, 48, and 60 months

* 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

* Implant survival for surgical revision at the level of intervention assessed throughout 60 months of follow-up.

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

Study design

A multi-centre, prospective, post marketing surveillance study. Subjects randomized in this amended protocol will receive a DISCOVER artificial cervical disc.

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 a cage that is placed in the space where the disc was, together with a plate fixed to the bone above and below the cage. Allograft (bone donated from another patient) is added to allow new bone to grow, and join together the affected bones in the neck. Cervical Carbon Fibre Reinforced Polymer Interbody Fusion cage (CFRP I/F CAGE®) is the name of the cage being used in this research study. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion Criteria;i) Male or female subjects, aged between 18 and 65 years inclusive.;ii) Subjects who are able to give voluntary, written informed consent to participate in this clinical investigation and from whom consent has been obtained.;iii) Subjects who, in the opinion of the Clinical Investigator, are able to understand this clinical investigation, co-operate with the investigational procedures and are willing to return to the hospital for all the required post-operative follow-ups.;iv) Objective evidence of cervical disc disease in one vertebral level between
C3-C7 defined as one or more of the following:
* Shoulder and/or arm pain in a radicular distribution resulting from herniated disc or bony osteophytes (Consistent with diagnostic imaging including Axial CT, CT Myelogram, MRI and/or plain films)
* Subjects with myeloradiculopathy resulting from mild spinal cord compression and nerve

root impingement;v) Unresponsive to documented non-surgical management for * 6 weeks and/or presents with progressive symptoms of nerve root or spinal cord compression in the face of continued non-surgical management (e.g., physical therapy, medication therapy, corticosteroid injections, etc.).;vi) Minimum Neck Disability Index score of *30 % (15/50 points)

Exclusion criteria

Exclusion Criteria;i) Subjects who, in the opinion of the Clinical Investigator, have an existing condition that would compromise their participation and follow-up in this clinical investigation.;ii) Subjects who are pregnant, lactating or wishes to become pregnant within the duration of the study.;iii) Subjects who are known drug or alcohol abusers or with psychological disorders that could affect follow-up care or treatment outcomes.;iv) Subjects who have participated in a clinical investigation with an investigational product in the last 30 days.;v) Subjects who are currently involved in litigation and seeking permanent disability status for any injury to the spine (subjects involved in litigation and seeking reparation for lost wages, medical expenses can be included);vi) Subjects with significant degeneration at more than one cervical level (e.g. DISH, ankylosing spondylitis, congenital abnormality, rheumatoid arthritis);vii) Subjects who have had any prior surgery at the level to be treated (subjects with a prior Laminotomy at the level to be treated may be included in the study) viii) Subjects who have marked cervical instability on lateral or flexion/extension x-rays defined as translation *3mm and/or *11 degrees of rotational difference to either adjacent level;ix) Subjects who have presence of systemic infection or infection at the site of surgery;x) Any significant illness (e.g HIV or metastatic cancer of any type) that decreases the probability of the subject*s survival to the five-year follow up of the study. ;xi) Subjects who have been diagnosed with a condition or require postoperative medication(s) that may interfere with bony/soft tissue healing;xii) Subjects who have been diagnosed with Osteoporosis, Osteopenia, other metabolic bone disease or endocrine disorder known to affect osteogenesis. ;xiii) Subjects with pre-existing neurological abnormalities other than deficits produced from the spinal lesion (e.g., MS, Parkinson*s, CVA, diabetic neuropathy, peripheral neuropathy).;xiv) Subjects with morbid obesity defined as a BMI of *40 or more than 100 lbs (45.4kg) over ideal weight. (See Appendix II for BMI chart.);xv) Subjects with any known allergy to titanium metal, polyethylene
xvi) Subjects who have had prior fusion surgery at any level(s) (C1-T1);xvii) Subjects with kyphosis >-15 degrees evaluated using the Cobb angle measurement;xviii) Subjects with Significant cervical degenerative disease characterized by bridging anterior osteophytes, significant loss of disc space height (3mm or less), sclerotic facets, large posterior osteophytes, autofusion of other cervical levels, and degenerative retrolisthesis. Spinal diseases such as DISH, ankylosing spondylitis, congenital abnormality, and rheumatoid arthritis, should also be excluded;xix) Subjects undergoing treatment with a bone growth stimulator, which cannot be discontinued prior to enrollment in the study.;xx) Significant kyphotic deformity or significant reversal of lordosis.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2008
Enrollment:	18
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	21-04-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-10-2009
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
CCMO	NL21563.008.08