Cervical Arthroplasty Study: Cadisc*-C Total Disc Replacement

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The objectives of this study are to evaluate the safety and performance of the Cadisc*-C Total Cervical Disc Replacement Device in the surgical replacement of the cervical intervertebral discs (C3 to C7) for patients requiring surgical intervention...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON36805

Source
ToetsingOnline

Brief title
CASCADE

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
Surgical replacement of the cervical intervertebral discs (C3 to C7) for patients requiring surgical intervention for total cervical disc replacement for the treatment of discogenic pain (neck/shoulder/arm)

Research involving
Human

Sponsors and support

Primary sponsor: Clinical and Regulatory Affairs
Source(s) of monetary or material Support: Ranier Technology Ltd

Intervention

Keyword: Cervical, Disc, Multicenter, Replacement

Outcome measures

Primary outcome

The primary endpoint is a composite of the proportion of subjects who show clinical success, where success is described by the following components:

1. An improvement of 15 points on the arm VAS score at 3 months post-operatively

2. An improvement of 15 points on the NDI scale at 3 months post-operatively, compared to baseline

3. No significant adverse events

A participant is defined as a success if:

• 1 and 3 are true, or

• 1 and 2 and 3 are true.

Secondary outcome

1. The effect on the subjects* visual analogue score (VAS) pain score at 6 weeks, 3, 6, 12 and 24 months post-treatment as compared with pre-treatment (baseline) scores.

2. The number of participants who show an improvement of 15 points on the NDI scale at 6 weeks, and 6, 12 and 24 months post-surgery, compared to baseline, i.e. pre-operative, scores, expressed as a proportion.

3. The mean and 95% confidence interval NDI scores at 6 weeks, 3, 6, 12 and 24 months post-treatment as compared with pre-treatment (baseline) scores.

4. The effect on physical functioning and bodily pain scores from the SF-36 and EQ-5D patient questionnaire at 6 weeks, 3, 6, 12 and 24 months post-treatment

as compared with pre-treatment (baseline) scores.

5. The effect on the participants* disc height at the operative disc level as determined by lateral radiographs at 3, 6, 12 and 24 months post-treatment as compared with pre-treatment (baseline) levels.

6. The effect on the subjects* disc height at the operative disc level as determined by lateral radiographs at 3, 6, 12 and 24 months post-treatment as compared with immediate post-treatment (t = 0) levels.

7. The effect on the subjects* motion at the operative disc level as determined by flexion/extension radiographs at 6, 12 and 24 months post-treatment as compared with pre-treatment (baseline) levels.

8. Proportion of surgical revision at the level of intervention within 3, 6, 12 and 24 months.

9. Proportion of patient expressing a preference for surgery at 12 and 24 months.

10. Degree of heterotopic ossification forming post operatively from 3 to 24 months.

11. Degree of adjacent segment disease.

Study description

Background summary

Ranier Technology Limited (RTL) presents for clinical study a cervical disc replacement medical device, CadiscTM-C, intended for patients with neck and arm pain associated with degenerative disc disease.

Neck pain has become a public health problem with high prevalence rates in modern society . After the age of 40 years, almost 60% of the population has

radiographic evidence of cervical spine degeneration. However, prevalence rates of neck pain have been reported up to 13.8% . About 90% of patients respond positively to conservative, non-surgical treatment; however, a minority of patients with chronic disabling degenerate disc disease (DDD) require surgical intervention. Current therapies for patients with neck and arm pain associated with degenerative disc disease who have not responded to conservative treatment include fusion and partial or total disc replacement (TDR). Fusion involves removal of the diseased disc and fusion of the adjacent vertebrae, with or without an augmenting implant. TDR involves removal of the diseased disc and its replacement with a disc replacement device. Both treatments are effective in curing pain but each has drawbacks. Vertebral fusion restricts the range of motion of the patient and means that adjacent discs are subjected to abnormal mechanical loads which in turn can lead to degeneration over time of those discs. TDR overcomes these issues to some extent but the presently available first generation devices have limited axial compression and multi-component articulating surfaces, meaning that wear particles can be generated in situ with potential for long term device failure. There have also been issues with stress fracturing of the vertebral body associated with the fixation features of the TDR hard metal end plates.

Study objective

The objectives of this study are to evaluate the safety and performance of the Cadisc*-C Total Cervical Disc Replacement Device in the surgical replacement of the cervical intervertebral discs (C3 to C7) for patients requiring surgical intervention for total cervical disc replacement for the treatment of degenerative disc disease in the cervical spine.

Safety will be assessed by review of frequency of revision and other adverse device events as in the context of other marketed devices as published in the literature. Performance information will be collated from patient derived Outcome Scores: the Neck Disability Index (NDI), EQ5D, Pain VAS and SF36. Radiographic data will be gathered to demonstrate both safety and performance of the device in terms of initial positioning, subsequent migration, implant integrity, range of motion and correction & maintenance of disc height.

Should the safety and performance of the device be demonstrated then the information derived from the above test will form the basis of device claims.

Study design

This is an international, multi-centre, prospective, open non-randomised study design. Patients will be included in the study after giving written informed consent and will be subject to the routine surgical and post-operative care at each participating centre. Additionally, local ethics and Competent Authority approval or notice of no objection will be obtained in each centre prior to

recruitment there.

The recruitment phase is estimated as 6 months. Assessments are to be carried out as per routine practice where possible, but will correspond to the following schedule: pre-operative; peri-operative; and post-operatively at 6 weeks, 3 and 6 months, followed by a further assessment at 12 months and annually thereafter to two years post-operatively, i.e. 12 & 24 months. The study is aimed at evaluating safety and performance for CE Marking of the device and an interim analysis will be performed after 50 patients have reached 3 months follow-up, but additionally, all those patients having reached 6 months or more, will also be reported.

Performance of the Cadisc*-C will be assessed using a selection of validated of outcomes questionnaires (including Neck Disability Index (NDI), SF36 v 2.0 and Euroqol (EQ5D v 1.0) & Pain Visual Analogue Scales for neck and for arm (VAS). Re-operation and other adverse device events will be assessed to measure safety. Patients will be screened preoperatively to ensure psychological factors of condition and suitability for entry to study linked to inclusion and exclusion criteria.

Intervention

Not Applicable

Study burden and risks

Participation in the study per se, does not introduce any additional risk to the patient because the study will follow normal routine practice at each hospital in terms of surgical technique, radiographic review and follow-up visits.
A further potential benefit to a patient from participation in the study is linked to data collection, and regular review, which could identify any potential problems earlier than would normally clinically present. Indeed there is some evidence to suggest that participants in a trial have better outcomes than those in routine clinical practice .
Many hospitals already collect some form of outcome score data for their patients either in the form of SF36, GPOS or NDI so the only inconvenience for the patients will be the need to complete two or three questionnaires instead of one.
The key potential benefit of this next generation device is that it has been engineered to match closely the physiological performance of a natural disc, more so that is the case for existing disc with metallic components. In this way it is possible that the treatment option of a Cadisc*-C will yield excellent outcomes and resolve the symptoms of neck, shoulder and arm pain in trial participants.
Risk management; analysis, evaluation and control of all potential sources of

hazard and of failure modes has been conducted according to the benchmark standard ISO 14971 and with reference to the experience of other marketed devices (the output of which is available upon request). In summary, this output shows that none of the reviewed Failure Modes pose an unacceptable risk either because of the anticipated low probability of occurrence or because any problems resulting from failure would generally be considered of low risk to the patient when weighed against the potential benefits, described above. However, as is the case with all spinal implants, it is possible that the surgery will not completely relieve all patients* pain.
Subjects will be advised of the potential risks and benefits associated with this investigation in the Patient Information Sheet which will be approved by the local Research Ethics Committee, prior to enrolment.

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

1. Skeletally mature patients (aged 18 years 65 years),
2. Not pregnant or lactating at the time of surgery,
3. Has cervical disc syndrome as defined as radiculopathy with or without accompanying cervical pain with symptomatic nerve root compression documented by patient history, clinical examination and confirmed by MRI or CT/myelogram, showing cervical disc herniation or nerve root entrapment
4. One level cervical disc syndrome where the implantation may or may not be adjacent to a pre-existent fusion
5. Proposed surgical level at C3- C7 inclusive,
6. Unresponsive to conservative, i.e. non-surgical management, such as pharmaceutical, physiotherapy or surgical micro-discectomy/decompression for six weeks or presence of progressive symptoms or signs of cord compression,
7. No previous surgical procedures at the involved level or any planned surgical procedure at the involved or adjacent level other than outlined in inclusion criterion 4,
8. Arm Pain score of >= 20 based on Visual Analogue Scale, may be with Preop Neck Disability index score >= 30
9. Capable of and willing to comply to the study protocol in the opinion of the Investigator, including a is willingness to return to the hospital for all the required post-operative follow-up visits,
10. Capable of and willing to provide voluntary, written informed consent to participate in this investigation and from whom written consent must be obtained prior to enrolment.
11. Mild signs of myelopathy without change to the spinal cord as seen on T2-MRI

Exclusion criteria

a. Arm pain confirmed as non discogenic in origin
b. Undergone previous cervical spinal surgery at the index level that could affect the trial outcome (e.g., disc replacement or previous fusion),
c. Radiographic evidence of facet degeneration or severe facet disease,
d. Active infection or metastatic, autoimmune or terminal disease
e. Osteoporosis, osteopenia or other metabolic bone disease or endocrine disorder known to affect osteogenesis,
f. Significant spinal deformity such as osteophytes, sclerotic facets,
g. Pre-existing neurological abnormalities or other deficits, e.g. Parkinson*s disease, diabetic neuropathy, MS, cerebro-vascular accident, peripheral neuropathy,
h. Significant loss of disc height >50%
i. Clinically compromised vertebral bodies at the affected level due to current or past trauma
j. Subject is skeletally immature as determined by the investigator
k. Instability of the cervical spine as defined radiographically (Panjabi & White [1990]), if suspected:
a. Flexion extension saggital plane translation >3.5mm or 20% and saggital plane rotation > 20°, OR

b. Resting X-rays: saggital plane displacement > 3.5mm or 20% and relative saggital plane angulation >11º
l. Myelopathy with change to the spinal cord as seen on T2-MRI
m. Morbid Obesity BMI>40
n. Unwillingness or inability to give consent or adhere to the follow-up programme
o. Drug or alcohol dependency
p. Currently involved in injury litigation
q. Known allergy to any of the implant materials
r. Subject has participated in another clinical investigation or study with an investigational medical device within the last 60 days
s. Concomitant medications that are known significantly to interfere with bone/soft tissue healing, e.g. steroids.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2011
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Cadisc□-C
Registration:	No

Ethics review

Approved WMO

Date:	22-03-2011

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL33578.075.11