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A Clinical Trial Evaluating a Total Disc Replacement in Patients with Cervical Disc Disease

Submission date 21/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/06/2010	**Overall study status** Completed	
Last Edited 07/06/2010	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NUVA-CP-0904

Study information

Scientific Title
A Non-Randomised Controlled Clinical Trial Evaluating a Total Disc Replacement in Patients with Cervical Disc Disease

Study objectives
This study will be a non-randomized trial consisting of patients with single level (C3 to C7) symptomatic cervical disc disease who have not previously received fusion surgery at the same level, and have failed to improve with conservative treatment for at least 6 weeks prior to enrollment, or who present with progressive neurological symptoms or signs in the face of conservative treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The medical ethics committee of El Centro Medico Hospital del Prado approved on the 15th of April 2010 (ref: NUVA-CP-0904)

Study design
Non-randomized multicentre historically controlled

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Degenerative Disc Disease

Interventions
Cervical spinal reconstruction

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Individual patient success at 24 months, tested using Blackwelders method for testing non-inferiority with delta of 10%.
Success is defined as:
1. Improvement in the Neck Disability Index (NDI) by ≥ 15 points at 24 months compared to Baseline
2. No device failures requiring revision, re-operation (including supplemental fixation), or removal from the patient
3. No device-related serious adverse event and
4. Maintenance or improvement of neurologic status (based on sensory, motor, and reflex assessment scores and observational gait analysis)

Secondary outcome measures
1. Range of Motion (ROM) defined as more than 3 degrees total flexion / extension. If the ROM is less than or equal to 3° the patient will be defined as having 'non-motion'
2. Fusion (defined as ≤ 3° of ROM at the operative level, absence of radiolucent lines around ≥ 50% of the implant, and no displacement or migration of the device (defined as > 3mm abnormal movement measured from AP and lateral plain films)
3. SF-36 improvement of ≥ 15% at 24 months compared to Baseline
4. Visual analog pain scale (VAS) improvement of ≥ 20 mm at 24 months compared to Baseline
5. Disc height from the lateral radiograph showing maintenance or improvement from Baseline at 24 months

Overall study start date
26/05/2010

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Age: 18-60 years of age (inclusive and skeletally mature)
2. A diagnosis of symptomatic cervical disc disease, defined as image-confirmed pathology: herniated disc, spondylosis, and/or loss of disc height. Spondylosis is defined as image-confirmed disc desiccation, loss of disc height, bridging osteophytes, and/or uncovertebral arthrosis. Loss of disc height is specified as a measurement of at least 25% less than an adjacent nonsymptomatic level, but with a minimum of 1mm height remaining
3. Functional neurological deficit (i.e., exhibits at least one sign associated with cervical level to be treated, including abnormal reflex, decreased motor strength, abnormal dermatome sensitivity, or pain in a dermatomal distribution);
4. Symptomatic level is C3-4, C4-5, C5-6 or C6-7 (one level)
5. Preoperative Neck Disability Index (NDI) ≥ 30 points (considered moderate disability; Vernon 1991);
6. Unresponsive to conservative treatment for ≥ 6 weeks, and/or exhibits progressive symptoms and/or signs of nerve root and/or spinal cord compression in the face of conservative treatment
7. Not pregnant, nor interested in becoming pregnant within the follow-up period of the study
8. Willing and able to comply with the requirements defined in the protocol for the duration of the study
9. Signed and dated Informed Consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Prior cervical fusion, prior laminectomy (prior cervical laminotomy that has not violated the facets need not be excluded), and/or prior cervical facetectomy at the operative level
2. Requiring surgical treatment that would leave the patient with a postoperative deficiency of the posterior elements
3. Signal changes in the cord on preoperative T2-weighted MRI and/or clinically significant myelopathy which would be described as gait disturbance, loss of manual dexterity, or bowel or bladder incontinence/retention.
4. Radiographic signs of significant instability at operative level (> 3mm translation, > 11° rotation different from adjacent level)
5. Bridging osteophytes or motion < 3°
6. Radiographic confirmation of significant facet joint disease or degeneration
7. Chronic neck or arm pain of unknown etiology
8. Cervical fracture, anatomic anomaly, or deformity (e.g. ankylosing spondylitis, scoliosis) at the levels to which the prosthesis will be attached
9. Severe spondylolisthesis (greater than grade 1)
10. Endocrine disorders or connective tissue diseases
11. Rheumatoid arthritis or other autoimmune disease
12. Progressive neuromuscular disease, e.g., muscular dystrophy, multiple sclerosis
13. Chronic steroid users
14. Taking any medications or drugs in doses that are known to potentially interfere with the bone metabolism or soft tissue healing, which may include (but is not limited to) the following: inhaled glucocorticoids for asthma, corticosteroids, thyroid hormones, blood thinners (heparin, warfarin), gonadotropin-releasing hormone agonists for prostate cancer treatment, contraceptive medroxyprogesterone, lithium for bi-polar disorder treatment, anticonvulsants, aluminum-containing antacids, tetracycline
15. Osteoporosis to a degree that spinal instrumentation would be contraindicated (DEXA T-score less than or equal to -2.5; DEXA necessary only if patient exhibits risk factors for low bone mass as quantified in DEXA screening questionnaire)
16. Diabetes mellitus requiring insulin management
17. Presence of metastases or active spinal tumor malignancy
18. Body Mass Index (BMI) > 40
19. Active local or systemic infection, including AIDS, hepatitis

20. Having been enrolled in another investigational device study within the last 90 days
21. Having had another cervical device implanted that would interfere with the surgical approach, study or control device, or follow-up evaluations
22. Demonstrates 3 or more signs of nonorganic behavior, such as Waddells signs
23. History of substance abuse
24. Involved in spinal litigation
25. Mentally incompetent
26. Incarcerated

Date of first enrolment
26/05/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Mexico

United States of America

Study participating centre
1200 Hilyard
Eugene
United States of America
97401

Sponsor information

Organisation
Nuvasive Inc. (USA)

Sponsor details
7475 Lusk Blvd
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Sponsor type
Industry

ROR
https://ror.org/036dqy506

Funder(s)

Funder type
Industry

Funder Name
Nuvasive Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration