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NuNEC™ disc prosthesis versus Prestige® artificial cervical disc replacement: a pilot study

Submission date
09/03/2010

Recruitment status
No longer recruiting

Registration date
14/04/2010

Overall study status
Completed

Last Edited
06/06/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
As you age the discs between your neck bones lose their integrity, strength and movement, putting pressure on your nerves that can lead to neck and arm pain. Replacing these diseased discs with artificial discs can improve the pain and other problems associated with it. We are using two types of artificial disc replacement prosthesis in our hospital at present. The Prestige® disc prosthesis is made of metal, which can cause problems if MRI scans have to be performed. This prosthesis has been in use for many years and has had good results so far. The NuNEC™ disc prosthesis is a newer prosthesis and is made of a material called polyetherether-ketone (PEEK; a non-metal material). This is compatible with MRI and provides good images. The results so far are encouraging, and long-term results are awaited. This study is being conducted to compare the outcomes following these two types of disc replacement.

Who can participate?
Patients of any age with cervical degenerative disc disease

What does the study involve?
Participants are randomly allocated to undergo surgical disc replacement using either the NuNEC™ or Prestige® prosthesis. Neck and arm pain are assessed and x-rays are performed before surgery and at 6 weeks, 3 months, 6 months, 1, 2, 3, 4 and 5 years after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital of North Tees (UK)

When is the study starting and how long is it expected to run for?
May 2010 to May 2016

Who is funding the study?
North Tees and Hartlepool NHS Foundation Trust (UK)

Who is the main contact?
Mr Shabtai Friesem

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
NuNEC™ disc prosthesis versus Prestige® artificial cervical disc replacement: a prospective randomised controlled pilot trial

Study objectives
Is the clinical and radiological outcome following anterior cervical decompression disc replacement using NuNEC™ (PEEK on PEEK) prosthesis better than or same as Prestige® disc (metal on metal) replacement at short to long term follow-up (i.e., 6 months, 1, 2, 3, 4 and 5 years)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Prospective randomised controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cervical disc degeneration

Interventions
Anterior cervical decompression and disc replacement using either NuNEC™ or Prestige® cervical disc replacement.

Standard and accepted clinical and radiological parameters will be evaluated and compared pre-operatively and post-operatively at 6 weeks, 3 months, 6 months, 1, 2, 3, 4 and 5 years following surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Standard and accepted clinical and radiological parameters will be evaluated and compared pre-operatively and post-operatively at 6 weeks, 3 months, 6 months, 1, 2, 3, 4 and 5 years following surgery.

Clinical:
1. Visual Analogue score for neck pain (VAS-NP), from 0 = no pain, to 10 = extremely painful. This is a valid assessment tool to assess the effectiveness providing relief of neck pain which has been used in similar trials.
2. Visual Analogue score for arm pain (VAS-AP), from 0 = no pain, to 10 = extremely painful. This is a valid assessment tool to assess the effectiveness providing relief of neck pain which has been used in similar trials.
3. Neck Disability Index (NDI). Valid assessment questionnaire used to assess the effectiveness treatment in reducing neck pain, headaches and their influence on work, reading, lifting, sleeping and recreation, which has been used in similar trials in the past. An improvement in scores by 15 points in NDI is considered as good outcome following surgery.
4. 36-item short form health survey (SF-36). This is a validated assessment questionnaire used to assess the effectiveness of the treatment in improving the physical health, mental health and general overall wellbeing.

Radiological:
5. AP view (X-ray taken from front of neck) - to assess the prosthesis alignment
6. Lateral view (X-ray examination done from the side of the neck) - disc space measurements, kyphotic angle
7. Flexion/extension views (in addition) - radiological examination performed with the patient bending and extending the neck. These x-rays are performed 6 weeks onwards to ascertain the degree of movement at each level.
8. Adjacent level disc degeneration - magnetic resonance imaging (MRI)/computed tomography (CT) evaluation are performed to if adjacent/same level pathology is suspected at any time during follow-up.

These are the standard accepted imaging techniques used in other similar studies in the past.

Key secondary outcome(s)
Evaluated in the clinic, ranging from 6 weeks until the end of the trial:
1. Return to work
2. Clinical range of movement
3. Lack of movement (x-ray evidence of less than 4 degrees of dynamic motion)
4. Radiolucency more than 50% implant surface
5. Implant failure

6. Migration
7. Subjacent level disc degeneration
8. Adjacent-segment re-operation
9. Other common complications related to operation
10. Implant failure (breakage) or subsidence or radiological loosening causing neurological deficit at same level necessitating further surgery at same level is considered as failure of primary treatment

These are standardised secondary outcome measures as suggested by other similar studies.

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Single, double or multi-level cervical degenerative disc disease in any age group and sex
2. Failed conservative treatment which includes reduction of activities, physical therapy and anti-inflammatory medications
3. Acute severe grade motor or sensory deficit
4. Cervical radiculopathy - neck arthritis (wear and tear in the neck) causing arm pain because of pressure on nerves
5. Cervical myelopathy - neck arthritis causing arm pain and coordination problem because of pressure on spine or the nerves coming out of spine
6. Combination of cervical radiculopathy and myelopathy symptoms
7. Hard and soft disc pathology

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Participants unable to consent for the trial
2. Patients not willing to take part in the study
3. Patients participating in other clinical trials
4. Patients with previous surgery involving neck excluding injections
5. Severe facet joint arthritis involving cervical spine
6. History of discitis at the same level of surgery
7. Cervical instability: sagittal-plane translation greater than 3.5 mm, or sagittal plane angulation grater than 20 degrees at a single level
8. Lack of movement at the disc level

Date of first enrolment

01/05/2010

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital of North Tees
Stockton-on-Tees
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Sponsor information

Organisation
North Tees and Hartlepool NHS Foundation Trust (UK)

ROR
https://ror.org/04zzrht05

Funder(s)

Funder type
Government

Funder Name
North Tees and Hartlepool NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration