ISRCTN44347115 https://doi.org/10.1186/ISRCTN44347115

Total disc replacement versus fusion in cervical radiculopathy

Submission date	Recruitment status	[_] Prospectively registered
17/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2021	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims

Cervical radiculopathy is where a slipped disc or other bone pinches or irritates a nerve in the cervical spine (neck), resulting in pain. For patients with severe pain that lasts for more than 3 months, surgery can be effective and reduce symptoms. The standard procedure is to decompress the nerve by removing bone or disc material, and fuse the disc joint together. This is an accepted method with good results. Fusion may put more stress on the adjacent discs and may lead to increased degeneration (damage). Artificial discs have been developed as an alternative to fusion and may reduce degeneration and future problems at adjacent discs. The aim of this study is to compare the results of cervical fusion to disc replacement with an artificial disc implant.

Who can participate?

Patients between 18-60 years of age with cervical radiculopathy who have had symptoms for at least 3 months

What does the study involve?

Patients are randomly allocated to undergo decompression with either fusion or disc replacement. All participants are followed up to assess their symptoms after 3 months and 1, 2 and 5 years.

What are the possible benefits and risks of participating?

The use of artificial discs could prevent changes in adjacent discs and therefore lead to a better long term result. As disc replacement is a quite new method there are some potential risks, such as loosening or dislocation of the implant which might lead to further surgery.

Where is the study run from?

1. Stockholm Spine Center (Sweden)
2. Ryhov Hospital (Sweden)
3. Uppsala University Hospital (Sweden)

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

May 2007 to May 2012

Who is funding the study?
1. DePuy Spine, Inc. (Sweden)
2. Johnson & Johnson AB (Sweden)

Who is the main contact?
Dr Martin Skeppholm

Contact information

Type(s)
Scientific

Contact name
Dr Martin Skeppholm

Contact details
Stockholm Spine Center
Löwenströmska Sjukhuset
Upplands Väsby
Sweden
19489

Additional identifiers

Study information

Scientific Title
Total disc replacement versus fusion in cervical radiculopathy: a multicenter randomized controlled trial

Study objectives
Null hypothesis:
Disc replacement does not give a better outcome than fusion when cervical radiculopathy is treated with surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee, Stockholm, 31/03/2007, ref: 2006/1266-31/3

Primary study design
Interventional

Study design
Multicenter randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cervical radiculopathy

Interventions
1. Decompression and fusion of 1-2 cervical levels. Fusion is done with bone graft from iliac crest and anterior plate stabilisation
2. Decompression and disc replacement with Discover disc prosthesis (DePuy Spine)

Both groups are followed up at 3 months, 1 year, 2 years and 5 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Neck Disability Index (NDI) at 2 years follow up after intervention

Key secondary outcome(s)
1. Visual Analaogue Scale (VAS) neck/arm
2. EQ-5D
3. Dysphagia Short Questionnaire (DSQ)
4. Radiographic evaluation
5. Sick leave
6. Consumption of analgetics

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. At least 3 months of radiculopathy
2. Associated findings on Magnetic resonance imaging (MRI) at 1-2 levels in cervical spine
3. 18-60 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit

60 Years

Sex
All

Key exclusion criteria
1. Previous cervical surgery
2. Drug abuse or other obvious reason for bad compliance
3. History of Whiplash associated disorder (WAD) or severe cervical trauma
4. Rheumatoid arthritis, known malignancy, active infection or other systemic disease
5. Pregnancy
6. Cervical malformations

Date of first enrolment
20/05/2007

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Stockholm Spine Center
Upplands Väsby
Sweden
19489

Sponsor information

Organisation
DePuy Spine (Sweden)

Funder(s)

Funder type
Industry

Funder Name
DePuy Spine, Inc (Sweden)

Funder Name
Johnson & Johnson AB (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/01/2019	16/01/2019	Yes	No
Results article	follow up results	01/01/2021	22/01/2021	Yes	No
Results article	10-year results	17/12/2021	20/12/2021	Yes	No