

Prospective International multicentre Evaluation of Radiological and Clinical Effects of stand-alone polyetheretherketone (PEEK) intervertebral spacers for anterior cervical discectomy and fusion (ACDF)

Submission date 14/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/12/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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

Charité Projekt 88132022

Study information

Scientific Title

Prospective International multicentre Evaluation of Radiological and Clinical Effects of stand-alone polyetheretherketone (PEEK) intervertebral spacers for anterior cervical discectomy and fusion (ACDF): a prospective single-arm observational surgical implant trial

Acronym

PIERCE-PEEK

Study objectives

The study explores the following questions about the use of stand-alone polyetheretherketone (PEEK) cages in anterior cervical discectomy and fusion (ACDF) for patients with single-level cervical degenerative disc disease:

1. How much clinical improvement is there, in terms of pain and functioning, at 6- and 12-month follow-up?
2. What is the rate of radiological fusion at the operated level and how well does this correlate with clinical improvement?
3. What is the rate of short-term surgical revision (cage explantation, implant replacement, secondary ventral plating and/or additional dorsal stabilisation) due to implant subsidence or migration or device-related complications?
4. What is the rate and degree of adjacent-segment instability at the 1-year follow-up?
5. Do any particular patient characteristics (sociodemographic, clinical) or surgical factors predict better or worse clinical outcomes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Charité-Universitätsmedizin Berlin approved on the 22nd May 2006

Study design

International multicentre prospective single-arm observational surgical implant trial

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Cervical degenerative disc disease

Interventions

Single-level anterior cervical discectomy, as routinely performed in one of the five study centres. The surgeon is free to choose between four different PEEK cage intervertebral spacers. The cage size is selected according to the pre-existing intervertebral space height. Cages are implanted without any filling or supplemental instrumentation. The patients were mobilised immediately post-surgery and did not receive a neck collar.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Visual Analogue Scale (VAS) for patient-evaluated neck pain
2. Denis Pain Scale for clinician-evaluated neck pain
3. Neck Disability Index (NDI) for patient functioning
4. Japanese Orthopedic Association (JOA) questionnaire for assessment of neurological functioning

Measured at time of discharge from hospital (mean: 3 - 7 days post-surgery); 6 months post-surgery and 12 months post-surgery.

Secondary outcome measures

1. Radiological assessment of bony fusion
2. Radiological assessment of proper implant placement versus subsidence or migration
3. Radiological assessment of adjacent-level degeneration and/or instability
4. Documentation of complications

Measured at time of discharge from hospital (mean: 3 - 7 days post-surgery); 6 months post-surgery and 12 months post-surgery.

Overall study start date

01/09/2006

Completion date

01/01/2010

Eligibility

Key inclusion criteria

1. Age greater than or equal to 18 years, either sex
2. Cervical degenerative disc disease at a single level, C3/C4 - C7/Th1

3. Clinical signs of myelopathy or radiculopathy
4. Presence of neck/arm pain (cervicobrachialgia) and/or radicular deficits, which are refractory to conservative therapy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

Total final enrolment

356

Key exclusion criteria

1. Unable to provide informed consent to surgery
2. Osteoporosis, fractures, or concomitant tumours of the cervical vertebrae
3. Previous surgery in the affected level
4. Fusion of either immediately adjacent level (due either to a previous operation or natural history)
5. Kyphosis or instability/hypermobility in functional x-rays (because this was taken as an indication for ventral plating)
6. Systemic, spinal, or local infection (acute or chronic)
7. Known allergies or intolerance to the implant material PEEK

Date of first enrolment

01/09/2006

Date of final enrolment

01/01/2010

Locations**Countries of recruitment**

Argentina

Cyprus

Germany

Türkiye

Study participating centre
Charité-Universitätsmedizin Berlin
Berlin
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Sponsor information

Organisation

Deutsche Arthrose Hilfe e.V. (Germany)

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Sponsor type

Research organisation

Website

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Funder(s)

Funder type

Research organisation

Funder Name

Deutsche Arthrose Hilfe e.V. (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/04/2017	30/12/2020	Yes	No