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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

Registration date
22/04/2009

Last Edited
30/12/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Olaf Suess

Contact details
Charité-Universitätsmedizin Berlin
Campus Benjamin Franklin
Hindenburgdamm 30
Berlin
Germany
12200
+49 (0)30 8445 2550
olaf.suess@charite.de

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

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
Germany
12200

Sponsor information

Organisation
Deutsche Arthrose Hilfe e.V. (Germany)

ROR

https://ror.org/05e1k0d14

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Arthrose Hilfe e.V. (Germany)

Results and Publications

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