ISRCTN25558534 https://doi.org/10.1186/ISRCTN25558534

Comparison of the PEEK cage and an autologous cage in posterior lumbar interbody fusion

Submission date
06/01/2016

Recruitment status
No longer recruiting

Registration date
16/02/2016

Overall study status
Completed

Last Edited
30/11/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Degenerative disc disease in the lumbar spine (or lower back), otherwise known as lumbar degenerative disc disease, refers to a common condition in which a damaged disc causes lower back and leg pain that often requires surgery. For several decades, a treatment called posterior lumbar interbody fusion (PLIF) has been considered the best standard of care. This is a form of spinal fusion surgery which involves adding a bone graft from the iliac crest (a portion of bone from the patients pelvis) to an area of the spine that allows it to grow between two vertebrae to prevent that portion of the spine from moving. It does this by inserting a cage, often made from a synthetic material called PEEK into the disc (intervertebral) space. The researchers doing this study are investigating whether a cage made from the bony projection found at the back of a vertebra (spinous process) and a portion of the vertebral bone called laminae (called a autologous cage using the lumbar spinous process and laminae, or ACSP) will yield similar clinical and radiological results to those obtained using a PEEK cage.

Who can participate?
Adults aged 30-70 suffering from lumbar degenerative disc disease and requiring surgery.

What does the study involve?
Participants undergoing PLIF surgery are randomly allocated to one of two groups. Those in group 1 receive the PEEK cage. Those in group 2 receive the ACSP cage. All participants are then followed up for at least 2 years where the success of their surgery is assessed at regular intervals.

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

Where is the study run from?
Xiamen University Southeast Hospital (China)

When is the study starting and how long is it expected to run for?
November 2008 to October 2013

Who is funding the study?
Xiamen University of Technology (China)

Who is the main contact?
Dr Bin Lin

Contact information

Type(s)
Public

Contact name
Dr Bin Lin

Contact details
Department of Orthopaedics, the 175th Hospital of PLA
Southeast Hospital of Xiamen University
269 Zhanghua Road,
Zhangzhou
China
363000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of the PEEK cage and an autologous cage made from the lumbar spinous process and laminae in posterior lumbar interbody fusion

Acronym
PLIF (posterior lumbar interbody fusion)

Study objectives
To evaluate the clinical efficacy of PLIF with the PEEK cage and the ACSP in lumbar degenerative disc disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Central Ethics Committee of Xiamen University Southeast Hospital, 03/09/2008, ref: 20081102

Study design
Randomized controlled prospective study

Primary study design
Interventional

Secondary study design
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 participant information sheet

Health condition(s) or problem(s) studied
Lumbar degenerative disc disease.

Interventions
Patients with lumbar degenerative disc disease were randomly assigned to either a PEEK (polyetheretherketone) cage or an autologous cage using the lumbar spinous process and laminae (ACSP). Monosegmental posterior lumbar interbody fusion (PLIF) was performed in all patients. Mean lumbar lordosis, mean disc height, visual analog scale (VAS) scores, functional outcomes, fusion rates and complication rates were recorded and compared. The patients were followed postoperatively for a minimum of 2 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
Functional outcome was assessed using the Kirkaldy–Willis criteria 3, 6, 12 and 24 months postoperatively and annually thereafter.

Secondary outcome measures
1. Visual Analogue Score (VAS) was obtained for low back pain both pre- and postoperatively at 2-year follow-up
2. Radiological assessment was recorded at at 3, 6, 12 and 24 months postoperatively and annually thereafter
3. Fusion status was evaluated by anteroposterior and lateral flexion and extension radiographs

Overall study start date
30/11/2008

Completion date
20/10/2013

Eligibility

Key inclusion criteria
1. Patients aged between 30-70 years
2. Disc pathology requiring surgical intervention for decompression
3. One intended level of interbody fusion between L3 and S1
4. Radiological evidence of instability, spondylolisthesis and the presence of degenerative stenosis, or symptomatic degenerative disc disease
5. Persistent or recurrent low back or leg pain lasting at least 6 months and resulting in a significant reduction of quality of life

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
69

Total final enrolment
69

Key exclusion criteria
1. Patients need for two or more levels of fusion
2. Active infection
3. Metabolic disease
4. Severe osteoporosis, symptomatic vascular disease
5. Previous spinal surgery other than a lumbar discectomy in L3-L4, L4-L5, or L5-S1
6. Any major psychological problem
7. The combination of degenerative scoliosis and degenerative or isthmic spondylolithesis
8. Morbid obesity
9. Smokers

Date of first enrolment
03/12/2008

Date of final enrolment
03/12/2010

Locations

Countries of recruitment

China

Study participating centre
Department of Orthopaedics, the 175th Hospital of PLA, Xiamen University Southeast Hospital
269 Zhanghua Road
Zhangzhou, Fujian
China
363000

Sponsor information

Organisation
Xiamen University

Sponsor details
422 Siming S Rd
Siming
Xiamen
China
361005

Sponsor type
Industry

ROR
https://ror.org/00mcjh785

Funder(s)

Funder type
University/education

Funder Name
Xiamen University of Technology

Alternative Name(s)
XMUT

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
China

Results and Publications

Publication and dissemination plan
Planning to publish results of trial soon in a peer reviewed journal.

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	30/08/2016	30/11/2020	Yes	No