

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

Submission date 06/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
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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 spondylolisthesis
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
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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