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A study on which kind of hemostatic sponges has a more effective hemostatic effect for patients taking posterior spinal fusion surgeries

Submission date
14/10/2016

Recruitment status
No longer recruiting

Registration date
25/10/2016

Overall study status
Completed

Last Edited
18/11/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Lumbar stenosis is a condition where there is a narrowing of the spinal canal (space in the spine that the spinal cord travels through) in the lower back. This narrowing puts pressure on the nerves that make up the spinal cord leading to pain in the legs. In some patients, the pain can be so severe that it can prevent them from walking and surgery is the main treatment option. Patients undergoing surgery on the spine are at risk of losing large quantities of blood during the surgery. This may lead to the need for blood transfusions after surgery which can extend their stay in hospital. Stablising blood flow during surgery is an important way of controlling blood loss and being able to perform the surgery well. In recent years, use of certain types of sponges have been a good way for controlling blood loss, however it is not known which is the most effective. The aim of this study is to compare the effectiveness of three different haemostatic (blood controlling) sponges on blood loss in spinal surgery patients.

Who can participate?
Patients with spinal stenosis who are suitable for spinal surgery.

What does the study involve?
Participants are randomly allocated to one of three groups. All patients are treated using standard surgical techniques and have their bleeding controlled by having the blood vessels that have been cut during surgery sealed off. They then have a sponge placed on the area which is either made from gelatin, or one of two types of cellulose (a plant material). Participants in all groups are then followed up for 48 hours after surgery to monitor blood loss.

What are the possible benefits and risks of participating?
Participants in all groups should benefit from lower levels of bleeding after surgery. There are no direct risks involved with participating.

Where is the study run from?
Peking Union Medical College Hospital (China)

When is the study starting and how long is it expected to run for?
November 2013 to December 2016

Who is funding the study?
Wuxi Biot Bio-technology co. Ltd (China)

Who is the main contact?
Mr Shugang Li

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized parallel trial on effects of different hemostatic sponges in posterior spinal fusion surgeries

Study objectives
The aim of this study is to assess the impact of three different hemostatic materials on operative blood loss in spinal fusion surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Peking Union Medical College Hospital Ethics Committee, 11/06/2014, ref: HS2014046

Study design
Three-arm randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Spinal surgery

Interventions
Participants are randomly allocated to one of three groups using a simple equal probability randomization scheme. All participants undergo posterior lumbar decompression, internal fixation or bone graft fusion surgery by the same surgeon using standard techniques.

Group A: Following decompression post-operative bleeding is controlled using bipolar electrocautery, after which a Stypro hemostatic sponge is placed on the surface of the spinal dura mater.
Group B: Following decompression post-operative bleeding is controlled using bipolar electrocautery, after which a Collagen hemostatic sponge is placed on the surface of the spinal dura mater.
Group C: Following decompression post-operative bleeding is controlled using bipolar electrocautery, after which a Gelatin sponge is placed on the surface of the spinal dura mater.

Participants are followed up for 48 hours after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Postoperative drainage is measured using a measuring cylinder over the first 24 hours after surgery, the second 24 hours after surgery.

Secondary outcome measures
Intraoperative estimated blood loss (EBL) is calculated on the basis of surgical sponges soaked and volume in suction canisters, subtracting irrigation fluid added to the surgical field immediately after surgery.

Overall study start date
01/11/2013

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Lumbar stenosis
2. Disc disease
3. Instability (e.g. grade I-II spondylolisthesis, spondylolisthesis /spondylolysis)
4. Indicated for spinal surgeries
5. Aged 50 years and over

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Severe medical comorbidities such as osteoporosis, anemia and cardiovascular disease
2. Involvement of more than three surgical levels
3. Patients had abnormal prothrombin time (PT), partial thromboplastin time (PTT) and International Normalized Ratio (INR)
4. Patients were taking anti-platelet aggregates such as Aspirin or other anticoagulants

Date of first enrolment
30/06/2014

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
China

Study participating centre

Peking Union Medical College Hospital
No.1 Shuai Fu Yuan, Wang Fu Jing Street, Beijing, China.
Beijing
China
100170

Sponsor information

Organisation
Peking Union Medical College Hospital

Sponsor details
Department of Orthorpaedic Surgery
No.1 Shuai Fu Yuan
Wang Fu Jing Street
Beijing
China
100730

Sponsor type
Hospital/treatment centre

Website
http://www.pumch.cn/Index.html

ROR
https://ror.org/04jztag35

Funder(s)

Funder type
Industry

Funder Name
Wuxi Biot Bio-technology co. Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Derong Xu (xuderong19880001@163.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		15/10/2016	26/10/2016	No	No
Results article		12/12/2016	18/11/2024	Yes	No