

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/11/2024	Condition category Surgery	<input type="checkbox"/> 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. Stabilising 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
Mr Shugang Li

Contact details
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/04jztag35>

Funder(s)

Funder type

Industry

Funder Name

Wuxi Biot Bio-technology co. Ltd

Results and Publications

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?
Results article		12/12/2016	18/11/2024	Yes	No
Basic results		15/10/2016	26/10/2016	No	No