

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

<b>Submission date</b> 14/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2024	<b>Condition category</b> 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**  
Department of Orthopaedic Surgery  
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100170

## 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 Orthopaedic 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?
<a href="#">Basic results</a>		15/10/2016	26/10/2016	No	No
<a href="#">Results article</a>		12/12/2016	18/11/2024	Yes	No