

# Open surgery or minimally invasive blood vessel closure for hemorrhage control of pelvic fractures

**Submission date**  
21/07/2015

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
03/08/2015

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
29/10/2015

**Condition category**  
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

## Plain English summary of protocol

### Background and study aims

Massive bleeding after severe trauma with pelvis bone fractures is a fatal condition if not treated urgently. Both open surgical bleeding control and minimally invasive clotting of bleeding vessels are well established methods to deal with this condition. Until now it is unclear which method is superior. This study aims at comparing mortality, complications and treatment delay for the two methods.

### Who can participate?

Adult patients between 18 and 65 years of age with pelvic fracture, severe multiple injuries, and massive blood loss are included in this study. Due to the acute selection of patients, no active recruiting of patients will be performed.

### What does the study involve?

This study compares angioembolization and retroperitoneal pelvic packing for bleeding due to pelvic fractures. For angioembolization a wire is placed in a blood vessel and guided by x-ray to the bleeding vessel, which can be clotted from inside. Retroperitoneal pelvic packing uses an open surgical approach, where the bleeding vessels are ligated (tied off) and/or directly compressed. Sometimes patients with angioembolization require additional pelvic packing and vice versa. If necessary this secondary procedure will be performed and registered. Apart from this intervention all patients will receive the same treatment.

### What are the possible benefits and risks of participating?

Patients enrolled in this study will be followed meticulously and will thus receive maximum attention of the surgical team. Until now there are no studies documenting one method being superior over the other. Common adverse effects of angioembolization are injection site infections and allergic reactions to contrast media (substances used to improve images of the inside of the body in medical imaging). The most common adverse event of pelvic packing is a deep infection.

Where is the study run from?

This is a single-center study, run by the Shandong Provincial Hospital in Jinan, China.

When is the study starting and how long is it expected to run for?

February 2003 to February 2013.

Who is funding the study?

This study has no external funding. The treatment costs are covered by the Chinese government.

Who is the main contact?

Prof. Zhou Dongsheng

Tel: New Hospital: +86 (0)531 6877 3195, Old Hospital: +86 (0)531 6877 6382

## Contact information

### Type(s)

Public

### Contact name

Dr Yohan Robinson

### Contact details

Uppsala University Hospital

Department of Surgical Sciences

Uppsala

Sweden

75332

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Retroperitoneal packing or angioembolization for hemorrhage control of pelvic fractures - quasi-randomized clinical trial of hemodynamically unstable patients with Injury Severity Score  $\geq 33$

### Study objectives

In patients with pelvic fracture uncontrollable bleeding is the major cause of death within the first 24h after injury. Early hemorrhage control is therefore vital for successful treatment.

Nowadays, recommended techniques for hemorrhage control in pelvic fractures are retroperitoneal pelvic packing and angioembolization, dependent upon the available technical staff and resources and the condition of the patient.

Is retroperitoneal pelvic packing or angiography superior with regard to in-hospital mortality, complications, required secondary procedures, or post-intervention blood loss? Which of these methods is the more rapid intervention in the acute setting?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Shandong University Institutional Review Board, January 2003, no. 201252

### **Study design**

Single-center interventional quasi-randomized controlled trial with parallel design

### **Primary study design**

Interventional

### **Secondary study design**

Quasi-randomized design

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Pelvic fracture

### **Interventions**

#### **Angiography (ANGIO)**

Patients with persistent hemodynamic instability (systolic blood pressure (SBP) <90 mmHg after the transfusion of 4 packed red blood cell (PRBC) units in the emergency department) are taken urgently to the angiography suite for pelvic angiography. These patients have to tolerate transfer to the suite. Patients receiving primarily angioembolization therapy are defined as the ANGIO group.

#### **Retroperitoneal pelvic packing (PACK)**

Indication for pelvic packing is persistent SBP <90 mmHg during the initial resuscitation period with 3000 ml of intravenous (IV) crystalloids and transfusion of 4 PRBC units. These patients are treated primarily with retroperitoneal packing, while angioembolization OR staff is unavailable, and are defined as the PACK group.

### **Intervention Type**

Procedure/Surgery

**Primary outcome measure**

In-hospital mortality

**Secondary outcome measures**

1. Complications
2. Time from admission to surgery
3. Surgical time
4. Days on ICU
5. Postoperative PRBC units administered
6. Secondary procedures.

**Overall study start date**

01/02/2003

**Completion date**

28/02/2013

**Eligibility****Key inclusion criteria**

Patients admitted with:

1. Multitrauma defined as Injury Severity Score (ISS) > 17
2. Dislocated pelvic fracture type B or C according to Tile on emergency department pelvic radiograph
3. Hemodynamic instability defined as systolic blood pressure (SBP) <90 mmHg after administration of 4 units of packed red blood cells (PRBC)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

56

**Key exclusion criteria**

1. Patients with monotrauma, or Injury Severity Score (ISS)  $\leq 17$
2. Age > 65 years
3. Age < 18 years

**Date of first enrolment**

01/02/2003

**Date of final enrolment**

28/02/2013

# Locations

## Countries of recruitment

China

## Study participating centre

**Shandong Provincial Hospital**

No. 9677, Jingshi Road

Jinan

Jinan

China

250021

# Sponsor information

## Organisation

Shandong University (China)

## Sponsor details

324, Jingwu Road

Jinan, Shandong

China

250021

## Sponsor type

University/education

## Website

<http://en.sdu.edu.cn>

## ROR

<https://ror.org/0207yh398>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Shandong Provincial Hospital (China)

**Funder Name**

Akademiska Sjukhuset

**Alternative Name(s)**

Uppsala University Hospital

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Sweden

## Results and Publications

**Publication and dissemination plan**

The trial results will be published in 2015

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2016		Yes	No