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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/07/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/08/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
29/10/2015	Injury, Occupational Diseases, Poisoning			

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

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

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 ≥ 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

Study type(s)

Treatment

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 primarly with retroperitoneal packing, while angioembolization OR staff is unavailable, and are defined as the PACK group.

Intervention Type

Procedure/Surgery

Primary outcome(s)

In-hospital mortality

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Patients with monotrauma, or Injury Severity Score (ISS) ≤ 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)

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

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?
Results article	results	01/02/2016		Yes	No