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

Submission date
21/07/2015

Recruitment status
No longer recruiting

Registration date
03/08/2015

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Contact information

Type(s)
Public

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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 ≥ 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 primarly 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) ≤ 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?
Results article	results	01/02/2016		Yes	No