ISRCTN38873803 https://doi.org/10.1186/ISRCTN38873803

Early experience with treatment of unstable pelvic fracture using a computer aided system

Submission date	Recruitment status	[_] Prospectively registered
09/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/12/2022	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Background and study aims
Pelvic fractures, especially the unstable pelvic fractures, are associated with massive hemorrhage or important organ injuries resulting in significant morbidity (disease) and mortality (death). The early reduction (a type of surgical procedure to try and fix the fracture) for the unstable pelvic fractures has been considered to be effective to improve the clinical results. However, the optimal early reduction technique for the unstable pelvic fractures remains controversial. This study uses a computer aided system to help treat the unstable fracture. The aim of this study is to verify the effectiveness and report early experience with reduction of the unstable pelvic fractures using a computer aided pelvic reduction frame.

Who can participate?
Adults aged 18 and older who have unilateral unstable pelvic fractures and displacements.

What does the study involve?
Participants undergo surgery for their unstable pelvic fracture using a computer aided reduction frame. Participants also undergo a CT scan (a type of imaging that uses x-rays to create a detailed image of the body) during the procedure to see the reduction quality. Based on this scan, a pelvic model is reconstructed and the differences between the model and the actual pelvis are calculated. The reduction precision of the fracture is measured and any complications are recorded.

What are the possible benefits and risks of participating?
The direct benefit for the patients taking part in the study include low complications rates, smaller incisions of the operations, and shorter rehabilitation period. The direct risks for the patients include higher radiation exposure from intraoperative CT scan.

Where is the study run from?
Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
January 2014 to February 2018

Who is funding the study?
Chinese PLA General Hospital (China)

Who is the main contact?
1. Professor Pei-Fu Tang (Scientific)
2. Dr Jing-Xin Zhao (Scientific)

Contact information

Type(s)
Scientific

Contact name
Prof Pei-Fu Tang

Contact details
Department of Orthopaedics
Chinese PLA General Hospital
28 Fuxing Road
Haidian District
Beijing
China
100853

Type(s)
Scientific

Contact name
Dr Jing-Xin Zhao

Contact details
Department of Orthopaedics
Chinese PLA General Hospital
28 Fuxing Road
Haidian District
Beijing
China
100853

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Early experience with reduction of unstable pelvic fracture using a computer aided reduction frame

Study objectives
The aim of this study is to verify the effectiveness and report early experience with reduction of the unstable pelvic fractures using a computer aided pelvic reduction frame.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethical Review Committee of Chinese PLA General Hospital, 01/01/2015

Study design
Prospective single-center single-group interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Unstable pelvic fracture

Interventions
This study is a prospective single-group interventional study. All the participants in this study are allocated to the treatment group. All participants undergo the surgery of unstable pelvic fracture using a computer aided reduction frame.

For evaluation of the reduction quality of the clinical application of the entire system, this series of patients are performed with a second intro-operative CT scan after reduction with the frame. Based on this second intro-operative CT scan data, the 3D pelvic model at the anatomical reduction position can be reconstructed. The residual translational and rotational differences between the actual and virtual anatomical reduction positions could be calculated. The operation time is also recorded for the quality control of this technique.

Participants receive the standard post surgical care.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The reduction precision of the unstable pelvic fractures is measured using the residual translational and rotational differences between the actual and virtual anatomical reduction positions of pelvis at the end of operations
2. The intra-operative complications, such as wound infection, nerve or vascular injury, are recorded and retrieved from the medical electric records after the operations

Secondary outcome measures
The mean duration for the setup of the frame, the virtual surgery simulation, and the reduction of the unstable pelvic fractures, were recorded by our researchers during operations.

Overall study start date
11/01/2014

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. The unilateral unstable pelvic fractures and displacements
2. Adults aged 18 or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
Bilateral unstable pelvic fractures or stable pelvic fractures.

Date of first enrolment

01/01/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
China

Study participating centre
Chinese PLA General Hospital
28 Fuxing Road
Haidian District
Beijing
China
100853

Sponsor information

Organisation
Chinese PLA General Hospital

Sponsor details
28 Fuxing Road
Haidian District
Beijing
China
100853

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan
Analysis of relevant data of this study has been carried out. The main results will be published in a high-impact peer-reviewed journal.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the study will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/02/2018	01/12/2022	Yes	No