Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Investigating the role of 3D printing technology in modeling pelvic fracture surgery

Protocol summary

Study aim

The aim of this study was to determine the use of 3D printing technology in bone modeling along with the usual CT scan imaging process. To compare the consequences of pelvic surgery with the presence or absence of 3D printing technology in bone molding.

Design

This study was a parallel randomized controlled trial study design. The sample size of the study is 60 patients that will be assigned to intervention and control groups using simple randomization method.

Settings and conduct

Patient outcomes will be assessed at 2, 4, and 8 weeks after imaging using surgery. This study will be performed in the orthopedic ward of Rasoul Akram hospital of Iran University of Medical Sciences. Because it is clear that the intervention processes are aware for both patients and physicians, blinding is not applicable in this study and also the outcomes are measured objectively and with the help of imaging, the bias caused by patient evaluation is minimized.

Participants/Inclusion and exclusion criteria

The main inclusion criteria are confirmation of pelvic fractures and age 18 to 80 years and non-inclusion criteria include pathological fractures, bone tumors and history of pelvic surgery.

Intervention groups

All patients undergoing pelvic surgery in this study will undergo CT scan imaging and 3D printing technology which is a routine process. Only for the intervention group, bone modeling will be done with 3D printing technology, but for the comparison group, the molding is routine.

Main outcome variables

Duration of surgery, accuracy of reduction in surgery, bleeding, complications of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047852N2**
Registration date: **2021-11-30, 1400/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-30, 1400/09/09**
Update count: **0**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Shayan Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 3375

Email address

amiri.shayan23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the role of 3D printing technology in modeling pelvic fracture surgery

Public title
3D-printing technology In fractures surgery
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of pelvic fracture by an orthopedic surgeon and imaging Age between 18 to 80 Patients consent to participate in the study
Exclusion criteria:
Pathological fractures Bone tumors Patients who have high underlying diseases due to the type of surgical fracture History of pelvic surgery
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After the participants were selected to study, we will use simple randomization method to assign participants to the groups for received intervention and comparison. The randomization process will be performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants will be identified by A and B so the assign of each patient in each group is unpredictable to other members of the research team. We will notify for the team manager after selecting each patient and they will determine the type of group each person according to the software output.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2020-11-11, 1399/08/21
Ethics committee reference number
IR.IUMS.REC.1399.786

Health conditions studied

1

Description of health condition studied
pelvic fracture
ICD-10 code
S32.8
ICD-10 code description
Fracture of other parts of pelvis

Primary outcomes

1

Description
Reduction accuracy
Timepoint
Weeks 2, 4 and 8 after surgery
Method of measurement
AP Imaging and Judet technique

2

Description
Complications
Timepoint
Weeks 2, 4 and 8 after surgery
Method of measurement
Infection, neurovascular injury, need for reoperation, limb length change, thromboembolism, chronic pain

Secondary outcomes

1

Description
Bleeding
Timepoint
During the surgery
Method of measurement
CC

2

Description
Duration of surgery
Timepoint

Duration of surgery

Method of measurement

Operating time in minutes

Intervention groups

1

Description

Intervention group: Bone mdeling will be performed for all patients in this group with 3D printing technology

Category

Diagnosis

2

Description

Control group:Bone modeling will be performed routinely for all patients in this group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Ali Yeganeh

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

1465613131

Phone

+98 21 6435 1234

Email

yeganeh.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein keyvani

Street address

Iran University of Medical Sciences, Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8687 2555

Email

tavakoli.m@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Yeganeh

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 3344 2345

Email

yeganeh.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Yeganeh

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 2255 6498

Email

yeganeh.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shayan Amiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 2222 5546

Email

amiri.shayan23@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Finding of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables

When the data will become available and for how long

Availability six months after the end of study

To whom data/document is available

Orthopedics

Under which criteria data/document could be used

Anyone who has a request for information about the results of this research

From where data/document is obtainable

Iran University of Medical Sciences

What processes are involved for a request to access data/document

By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results.

Comments