

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the surgical outcome of Intertrochanteric fracture with gamma nail insertion through inferior _center and centre-centre blade entry point.

Protocol summary

Study aim

Comparison the surgical outcome of Intertrochanteric fracture with gamma nail insertion through inferior _center and centre-centre blade entry point.

Design

The clinical trial includes two parallel study groups of 40 people with intertrochanteric fractures, who are randomly divided into intervention group 1 "applying inferior-center surgical technique" and intervention group 2 "applying center-center surgical technique". Randomization was done by Random Number Generator software. Samples are not blinded.

Settings and conduct

Patients under study who underwent gamma nail surgery were placed in one of the two lower methods. It will be placed in the back and center. Randomization in this research will be done with Random Number Generator software. After 6 months, the two groups will compare functional and radiological results. Place and time: Taleghani hospital in 2020-2022.

Participants/Inclusion and exclusion criteria

The study selected 30 patients (Both genders with age > 50 year) with intertrochanteric fracture. Patients should be able to walk independently before the fracture to be chosen for study. To prevent the distortion of information, the fractures should not be pathological type and the patient didn't have any previous fracture at the hip. All patients who don't follow these rules will exclude from the study.

Intervention groups

Applying the inferior-center surgical technique in the patients of intervention group 1 and applying the center-center surgical technique in the patients of the intervention group.

Main outcome variables

Functional and radiologic outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039188N4**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **retrospective**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

Reza Zandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

Email address

reza.zandi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2021-03-21, 1400/01/01

Trial completion date

2022-03-19, 1400/12/28

Scientific title

Comparison the surgical outcome of Intertrochanteric fracture with gamma nail insertion through inferior _center and centre-centre blade entry point.

Public title

Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) with Cognitive-Behavioral Therapy (CBT)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 50 years, with Intertrochanteric fractures.

Exclusion criteria:

History of intertrochanteric fracture and surgery in the past.

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization for 2 groups (1 Control, and 1 intervention groups), will done using software, 40 random numbers for each group. The surgeon can not play a role in predicting treatment of the disease, and choosing the type of treatment. Random sequence will generate by software. All admitted patients will be placed in one of the groups according to the pre-determined code.

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

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address

Koodakyar deadend, Daneshjou Boulevard, Yaman street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.SBMU.MSP.REC.1399.309

Health conditions studied

1

Description of health condition studied

Intertrochanteric fracture of femur

ICD-10 code

S72.14

ICD-10 code description

Intertrochanteric fracture of femur

Primary outcomes

1

Description

Functional outcomes

Timepoint

6 months after surgery.

Method of measurement

Visiting the patients

2

Description

Radiologic outcomes

Timepoint

6 months after surgery.

Method of measurement

MRI , X-Ray

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Surgical technique of Intertrochanteric fracture with gamma nail insertion through inferior _center blade entry point.

Category

Treatment - Surgery

2

Description

Intervention group: Intervention group: Surgical technique of Intertrochanteric fracture with gamma nail

insertion through center _center blade entry point.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Reza Zandi

Street address

Taleghani hospital, erabi Ave, Teman Ave, Chamran highway

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taleghanihospital@sbmu.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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koodakyar street, shahid shahriari square, chamran highway, tehran, iranK

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Dean.medicalschool@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Zandi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Full name of responsible person

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Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data including age, gender, history of diseases (Coronary artery disease, diabetes and Hypertension) and other considered variable will be shared after deidentification.

When the data will become available and for how long

Data will be available after publication.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Any type of analysis is prohibited unless the person in charge of the research is informed and would permit.

From where data/document is obtainable

Dr Reza Zandi Address: Aarabi St. - Yaman St. - Shahid Chamran Highway - Tehran Email: reza.zandi@sbmu.ac.ir

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

Doing the letter writing accordance with the person in charge of the research

Comments