Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Investigating the effect of polymethylmethacrylate cement in outcome of proximal humerus fractures

Protocol summary

Study aim
Investigating the effect of PMMA orthopedic cement on improving the jerk interval and daily activities after fixation of proximal humerus type 3 and 4 fractures with metaphyseal defects in patients over 50 years old.

Design
Clinical trial with control group, with parallel groups, single-blind, randomized block, on 60 patients. A software called Sealed Envelope was used for randomization

Settings and conduct
Patients referred to the orthopedic clinic of Vali Asr Arak Hospital with proximal humerus type 3 and 4 fractures with metaphyseal defects will be divided into two groups. In the intervention group, 500 cc of German BONOS bone cement will be used at the site of the metaphyseal defect during surgery. In the control group, cement material will not be used and routine surgery will be performed for the patients. In this study, the surgery will be performed by the supervisor and the orthopedic assistant will be responsible for the follow-up and follow-up of the patients. They do not know how to perform the surgery, so the participants are blinded. The corresponding assistant knows how to group patients and surgical procedures.

Participants/Inclusion and exclusion criteria
Entry criteria: type 3 and 4 proximal humerus fractures with metaphyseal defects; age over 50 years old.
Exclusion criteria: sensitivity to bone cement material; death of the patient.

Intervention groups
Patients with type 3 and 4 proximal humerus fractures with metaphyseal defects will be divided into two groups. In the intervention group, 500 cc of German BONOS bone cement will be used at the site of the metaphyseal defect during surgery. In the control group, cement will not be used and routine surgery will be performed for patients

Main outcome variables
Examination for infection; avascular necrosis; upper limb movements in the form of extension; flexion; external rotation; internal rotation; abduction and adduction.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230417057939N1**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date
2023-06-18, 1402/03/28

Registrant information
Name
MohameadHosein Bakhshi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 1313 6574
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mhosseinbakhshi92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-12, 1402/02/22

Expected recruitment end date
2023-09-03, 1402/06/12

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of polymethylmethacrylate cement in outcome of proximal humerus fractures

Public title

Investigating the effect of PMMA on the outcome of proximal humerus type 3 and 4 fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 3 and 4 proximal humerus fractures with metaphyseal defects Age over 50 years Absence of chronic kidney and liver disease Absence of cancer Informed consent to participate in the study

Exclusion criteria:

Allergy to bone cement Death of the patient Any cardiorespiratory arrest during surgery

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two intervention groups according to the order of arrival and based on the randomization sequence that will be produced in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, by using the block method random number generation software, the randomization sequence will be produced according to the required sample size for two groups. In the beginning, all the modes that can arrange 2 letters A and B in a block of 8 are produced. Then a block will be selected randomly and by placement among the blocks, and the arrangement pattern in that block will be used to allocate the participants. Then this block will be placed in the main container and another block will be selected again. All these works will be done with a software called Sealed Envelope. Using this method, concealment will also be observed. The concept of concealment is the unpredictability of assigning people to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single-blind - In this study, patients do not know how they are grouped and how their surgical procedures are performed, so the participants are blinded. The corresponding assistant knows how to group patients and surgical procedures.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Sardasht Ave., Chamran Blvd., Arak Town

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

IR.ARAKMU.REC.1402.003

Health conditions studied

1

Description of health condition studied

Proximal humerus fractures

ICD-10 code

S42.2

ICD-10 code description

Fracture of upper end of humerus

Primary outcomes

1

Description

Infection

Timepoint

Two weeks after surgery, 1 month after surgery and 3 months after surgery

Method of measurement

Observation

2

Description

Range of motion (ROM)extension; flexion; external

rotation; internal rotation; abduction and adductio

Timepoint

1 and 3 months after surgery

Method of measurement

Disabilities of the Arm, Shoulder and Hand; DASH Questioner

3

Description

Avascular necrosis

Timepoint

1 month after surgery and 3 months after surgery

Method of measurement

DASH questionnaire, graphic observation, examination

4

Description

Screw back out

Timepoint

Two weeks, one month after surgery and three months after surgery

Method of measurement

Graphic observation, examination

5

Description

Screw penetration

Timepoint

Two weeks, one month after surgery and three months after surgery

Method of measurement

Graphic observation, examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with type 3 and 4 proximal humerus fractures with metaphyseal defects, 500 cc of German BONOS bone cement will be used at the site of metaphyseal defects during surgery.

Category

Treatment - Surgery

2

Description

Control group: Patients with type 3 and 4 proximal humerus fractures with metaphyseal defects will not use cement, and routine surgery will be performed for patients.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Mehran Azami

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Valiasr Blvd., Valiasr hospital., Arak Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mohamad Hosein Bakhshi

Position
Orthopedic Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Clinical Study Report
Undecided - It is not yet known if there will be 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