

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of pinning treatment approach to casting in lateral condylar fractures of type 1 Homer on the range of motion of the elbow joint in children 3-10 years.

Protocol summary

Study aim

Determining and comparing the results of two therapeutic approaches of closed reduction with casting and closed placement with pinning in lateral condyle fracture of the humerus of children aged 3-10 years referred to Shahid Bahonar Educational and Medical Center in Kerman in 1401-1400

Design

This study is a clinical trial with a control group. The interventions are performed on two groups of 22 people in parallel, which are randomized and blinded in two directions. The random function of Excel software was used for randomization.

Settings and conduct

The two therapeutic approaches studied include the use of long-hand casts at 90 degrees of elbow flexion and reduction under the C-Arm and pin fixation, and the results of these two approaches will be compared. In this study, one-way statistical analyzer has been blinded.

Participants/Inclusion and exclusion criteria

In: Girls and boys in the age range of 3 to 10 years
Lateral condylar fractures type one out: Open fractures
Fractures with a higher degree Old fractures Dislocations and other fractures associated with type 1 fractures
Parents' dissatisfaction with the child's participation in the study And not referring for follow-up after treatment

Intervention groups

The study units are children aged 3-10 years of both sexes with lateral condyle fracture type 1, which after obtaining informed consent from parents in a simple random method in two groups of 22 people will enter the study. The two therapeutic approaches studied include the use of long-hand casts at 90 degrees of elbow flexion and implantation under the C-Arm device and pinning on the skin. The control group includes the group that underwent closed reduction and casting.

Main outcome variables

Rang of motion; Stiffness; Infection; Osteonecrosis; Cubitus varus; Bone union; Age; Gender.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210918052512N1**

Registration date: **2022-05-17, 1401/02/27**

Registration timing: **prospective**

Last update: **2022-05-17, 1401/02/27**

Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

Mohammad Nikukar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

mohammad.nikukar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of pinning treatment approach to casting in lateral condylar fractures of type 1 Homer on the range of motion of the elbow joint in children 3-10 years.

Public title
Comparison of pinning treatment approach to casting in lateral condylar fractures of type 1 Homer on the range of motion of the elbow joint in children 3-10 years.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Girls and boys in the age range of 3 to 10 years Lateral condylar fractures type one
Exclusion criteria:
Open fractures Fractures with a higher degree Old fractures History of underlying disease Dislocations and other fractures associated with type 1 fractures Children outside the age range studied Parents' dissatisfaction with the child's participation in the study And not referring for follow-up after treatment

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients are divided into two groups of 22 cases and control through simple randomization. The random feature of Excel software was used for randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, since blinding is not possible for physicians and patients, blinding is performed only for the analyst, so that the data of the two treatment approaches are identified with codes A and B so that it is possible to diagnose treatments for There is no analyst.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

West First, Sixth Alley, Vahshi Bafghi Street

City

Kerman

Province

Kerman

Postal code

7613744579

Approval date

2022-04-10, 1401/01/21

Ethics committee reference number

IR.KMU.AH.REC.1401.012

Health conditions studied

1

Description of health condition studied

Lateral condyle fracture

ICD-10 code

S42.45

ICD-10 code description

Fracture of lateral condyle of humerus

Primary outcomes

1

Description

Range of motion of the elbow joint

Timepoint

two weeks

Method of measurement

Goniometer

Secondary outcomes

1

Description

Bone union

Timepoint

monthly

Method of measurement

Radiography

2

Description

Elbow joint stiffness

Timepoint

Monthly

Method of measurement

Physical examination

3

Description

Wound infection at the site of the pins

Timepoint

two weeks

Method of measurement

Physical examination

4

Description

Bone necrosis

Timepoint

Monthly

Method of measurement

Radiography

5

Description

Cubitus varus

Timepoint

Monthly

Method of measurement

Radiography

Intervention groups

1

Description

Intervention group: After Closed Reduction under C_Arm and pinning, smooth pins with a diameter of 1.5 to 2 mm will be used according to the patient's weight and age.

Category

Treatment - Surgery

2

Description

Control group: Non-surgical treatment in one group will be performed using a long cast on 90 degrees of elbow flexion in the pronation position.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Shahab Elka

Street address

Shahid Dr. Mohammad Javad Bahonar Hospital,
Shahid Qarni St, Kerman Town

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kerman

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bahonarhospitalresearch@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Saeed Ahmadzadeh

Street address

Student Research Committee Headquarters, Sina Street, Jihad Boulevard, Somayeh Railway (Tahmasb Abad, Sina Street, Kerman Town

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Nikukar

Position

Resident

Latest degree

Medical doctor
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data of study participants can be shared after identifying individuals. This data includes: Therapeutic approach Range of motion of the elbow joint Elbow joint stiffness Wound infection at the site of the pins Bone necrosis Cubitus varus Bone burn Age Gender

When the data will become available and for how long

The data access period starts 6 months after the results are published.

To whom data/document is available

The text of the dissertation will be available to the public. Access to specialized data will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The analysis of the data of this study will be possible for the people who have access to it for scientific research in university centers. Public address for dissertation text For scientific researchers in academic and research centers

From where data/document is obtainable

The full text of the dissertation on the digital resources website of Kerman University of Medical Sciences at <https://centlib.uk.ac.ir/%D9%85%D9%86%D8%A7%D8%A8%D8%B9-%D8%AF%DB%8C%D8%AC%DB%8C%D8%AA%D8%A7%D9%84> and is available on the Ganj website at <https://ganj.irandoc.ac.ir>. To receive study data, correspondence with the Research Committee of Kerman University of Medical Sciences should be done at <https://ksrc.kmu.ac.ir/fa>.

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

After correspondence with the research committee of Kerman University of Medical Sciences and accepting the request and confirming the data, the data will be sent to

the individuals.

Comments