Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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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7619813159
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Email
src@kmu.ac.ir
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
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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