

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of closed and open reduction & fixation of supracondylar fractures of humerus in children

Protocol summary

Summary

The principle goal of the present study is the comparison of open and closed reduction and fixation in supracondylar humeral fracture in children. This is a randomized clinical trial. The sample includes 50 children, age range 3-10 years with supracondylar humeral fractures in an 18 month period, in Shohada orthopedic centre, Tabriz, Iran. They will undergo open or closed reduction and be followed for 3 month. Control radiologic imaging will be performed in 3 episodes, post operation, 2 week and 3 month later to evaluate carrying angle changes while considering cosmetic and functional outcomes and limitation of elbow joint in both groups. The main outcome to be assessed is the carrying angle. The supracondylar humeral fracture is the main inclusion criteria in this study and additional fractures and open fracture will be considered as exclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904244381N1**
Registration date: **2011-04-30, 1390/02/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-30, 1390/02/10

Registrant information

Name

Niloofar Esmaeli

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of closed and open reduction & fixation of supracondylar fractures of humerus in children

Public title

Comparison of closed and open reduction & fixation of supracondylar fractures of humerus in children

Purpose

Treatment

Inclusion/Exclusion criteria

The supracondylar humeral fracture is the main inclusion criteria in this study and additional fractures and open fracture will be considered as exclusion criteria.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht st

City

Tabriz

Postal code

Approval date

2009-12-21, 1388/09/30

Ethics committee reference number

8913

Health conditions studied

1

Description of health condition studied

Supracondylar Fracture Of Humerous

ICD-10 code

S42

ICD-10 code description

Fracture of shoulder and upper arm

Primary outcomes

1

Description

Carring Angle

Timepoint

In three Episodes, 1- Post operation 2-two weeks later 3- three months later

Method of measurement

Ruler And Protractor

Secondary outcomes

1

Description

Casmetic and functional outcores

Timepoint

In three Episodes, 1-post opeation 2- two weeks latear 3-three months later

Method of measurement

clinical

Intervention groups

1

Description

open surgical reduction

Category

Treatment - Surgery

2

Description

closed reduction

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Educational Center

Full name of responsible person

Dr. Ganjpour

Street address

Elgoli

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Shohada Educational Center

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty