

# 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)

##### Phone

+98 41 1332 7080

##### Email address

ganjpourj@tbzmed.ac.ir

##### 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

Dr. Ganjpour

##### Street address

Shohada Educational Center

##### City

Tabriz

#### 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*

Tabriz  
**Postal code**  
**Phone**  
+98 41 1385 9314  
**Fax**  
**Email**  
ganjpourj@tbzmed.ac.ir  
**Web page address**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Tabriz University Of Medical Sciences  
**Full name of responsible person**  
Dr. Niloofar Esmaili  
**Position**  
PhD Student  
**Other areas of specialty/work**  
**Street address**  
Education Center Shohada, Elgoli  
**City**  
Tabriz  
**Postal code**  
**Phone**  
+98 41 1332 7080  
**Fax**  
**Email**  
niloofar\_ek@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Ganjpour sales  
**Position**  
Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
Education Center Of Shohada, Elgoli  
**City**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University Of Medical Sciences  
**Full name of responsible person**  
Dr. Niloofar Esmaili  
**Position**  
PhD Student  
**Other areas of specialty/work**  
**Street address**  
Educational Center Shohada, Elgoli  
**City**  
Tabriz  
**Postal code**  
**Phone**  
+98 41 1332 7080  
**Fax**  
**Email**  
niloofar\_ek@yahoo.com  
**Web page address**

## 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*