

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the range of motion and clinical score of two legs in patients with clubfoot treated with Ponseti and modified ponseti method

#### Protocol summary

range of motion of ankle in all directions Dimeglio and Pirani functional score of foot

#### Study aim

Comparison of range of motion and performance score of two legs in patients with clubfoot treated with ponseti and modified ponseti Comparison of range of motion and performance score of the healthy foot with the patient foot in patients with unilateral clubfoot treated with ponseti or modified ponseti

#### Design

In this study, a clinical trial with a control group with parallel, randomized and double-blind groups on 100 children with clubfoot. Using the rand function of Excel, patients are divided into control and intervention groups. Except for the surgeon, none of the researchers and patients have access to the personal information of the patients and groups studied. The doctor evaluating the results of the treatment and other researchers are blinded by the study.

#### Settings and conduct

100 children with a clubfoot who referred to Tabriz Shohada Hospital from March until September 2021 after randomization in two groups of control and intervention are examined in two methods: ponseti and modified ponseti. Apart from the treating surgeon, others are blinded.

#### Participants/Inclusion and exclusion criteria

inclusion criteria: ; all children with clubfoot exclusion criteria: ; The age under 3 months and over 2 years ; A history of deformity other than clubfoot in the affected foot ; History of other treatments of clubfoot ; History of other congenital and neuromuscular diseases

#### Intervention groups

The control group treats with Ponseti method, which includes repeated manipulations of the ankle and the foot and casting, finally an Achilles tenotomy, and 3 weeks of the final casting. The intervention group is treated with a modified Ponseti method so that after the final tenotomy, instead of 3 weeks of casting, they undergo two periods of 3 weeks of casting.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201206049615N1**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

##### Registration date

2021-02-21, 1399/12/03

##### Registrant information

##### Name

Iman Habibi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3660 5459

##### Email address

ihabibee2008@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-21, 1400/01/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the range of motion and clinical score of two legs in patients with clubfoot treated with Ponseti and modified ponseti method

**Public title**

effect of ponseti method in treatment of clubfoot

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

all of the children suffering from bilateral clubfoot

**Exclusion criteria:**

age under 3 months age over 2 years history of other deformities in the lower extremities history of neuromuscular diseases history of clubfoot treatment with other methods

**Age**

From **3 months** old to **2 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

only the surgeon knows about the study groups the surgeon assigns a code to each patient and divides the patients into two groups called 1 and 2 (that are treated with ponseti or modified ponseti method) after obtaining informed consent from patients, they do not know anything about study groups and therapeutic methods. the researcher who evaluates the therapeutic results ( range of motion of ankle in all directions and Dimeglio and Pirani scores) and the analyzer who analyzes the research results do not know anything about the patient groups and just work with patient codes and group codes.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Approval date**

2020-09-14, 1399/06/24

**Ethics committee reference number**

IR.TBZMED.REC.1399.626

**Health conditions studied****1****Description of health condition studied**

clubfoot

**ICD-10 code**

M21.54

**ICD-10 code description**

Acquired clubfoot

**Primary outcomes****1****Description**

Range of motion of ankle

**Timepoint**

The range of motion of the ankle is measured before the intervention, immediately after the intervention, one month after the intervention, and then at intervals of 3 months to 6 months.

**Method of measurement**

The range of motion of the ankle in all sections is measured by one person so that the range of motion including Dorsiflexion, plantar flexion, eversion, inversion is measured by goniometer per unit of degree.

**2****Description**

ankle functional score

**Timepoint**

The ankle functional score is measured before the intervention, immediately after the intervention, one month after the intervention, and then at intervals of 3 months to 6 months.

**Method of measurement**

This score is measured by the global systems of Dimeglio

and Pirani introduced by scientists of the same name. Each of these systems gives a score based on the appearance of the patient's foot, the condition of the skin folds, the degree of deformity, the range of motion of the ankle in different directions, and the consistency of the deformity, which is compared before and after the intervention.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: This group of patients who suffer from clubfoot are first manipulated and plastered by a surgeon at two-week intervals, and after partial correction, they undergo Achilles tenotomy, after which they are plastered for three weeks. This treatment is called ponseti method, which is currently the most common treatment for clubfoot.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group: This group of patients who suffer from clubfoot are first manipulated and plastered by the treating surgeon at two-week intervals, and after partial correction, they undergo Achilles tenotomy, after which the cast is performed for three weeks. (As was done in the control group) but after three weeks the plaster is opened and unlike the control group, the manipulation is done again and the plaster is done again for three weeks.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Shohada hospital

##### Full name of responsible person

Hoseyn Aslani

##### Street address

Tabriz Shohada hospital, Golshahr Ave, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166617692

##### Phone

+98 41 3389 3336

##### Email

Shohadacrdu@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Hoseyn Aslani

##### Street address

Tabriz Shohada hospital, Golshahr Ave, Tabriz

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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

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

Tabriz University of Medical Sciences

##### Full name of responsible person

Hoseyn Aslani

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Tabriz Shohada hospital, Golshahr Ave, Tabriz

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hoseyn Aslani

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Tabriz University of Medical Sciences

**Full name of responsible person**

Hoseyn Aslani

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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**

All information about patients after their non-identification, study protocol, informed consent forms, data analysis processes, and codes used in them after the study in the form of a research project entitled "Comparison of range of motion and performance score of two The foot in patients with clubfoot treated with ponseti and modified ponseti method "will be available through the Vice Chancellor for Research of Tabriz University of Medical Sciences and also through the publication of an article with the same title in international journals.

**When the data will become available and for how long**

The access period starts from March 2023

**To whom data/document is available**

After uploading the data to the research vice-chancellor of Tabriz University of Medical Sciences, any person can access the data in coordination with the relevant unit. Also, after the publication of the article in international articles, all researchers and individuals can access the article according to the rules of the relevant journal.

**Under which criteria data/document could be used**

Access to the data will be possible after the coordination and approval of the Vice-Chancellor for Research of Tabriz University of Medical Sciences, and any use of data and study information is allowed after citation to the relevant references and citation to the names of the main researchers of the study.

**From where data/document is obtainable**

Applicants can send their application to the Vice-Chancellor for Research of Tabriz University of Medical Sciences at the following address to access the study information: International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, PO Box: 5165665931, Iran tel:0098 41 33363767

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

The request for access to the data, after being submitted by the applicants, will be reviewed by the Vice-Chancellor for Research of Tabriz University of Medical Sciences, and if the applicants agree to the above-mentioned conditions, it will be available to them.

**Comments**