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

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

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

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)

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+98 41 3660 5459

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hoseyn Aslani
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City
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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
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Person responsible for updating data

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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