

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison the Therapeutic Results of Conventional and Accelerated Ponseti Method in Children with Idiopathic Clubfoot

Protocol summary

Study aim

Comparison the therapeutic results of conventional and accelerated Ponseti method in children with idiopathic clubfoot

Design

Randomized, parallel group trial with blinded outcome assessment. Randomization was centralized with simple randomization with random number tables

Settings and conduct

Sixty patients with idiopathic clubfoot are randomly divided and evaluated into two intervention groups including conventional and accelerated ponseti method. In the conventional ponseti group, plasters are replaced weekly and on a fixed day and in the accelerated ponseti group, plasters are replaced two times in a week and on fixed days. Data analyses are blind to the groups allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria are children with idiopathic clubfoot and aged less than 1 year; The exclusion criteria are children with the syndromic and complex club foot, the relapsed club foot and history of any surgical or non-surgical procedure in other centers.

Intervention groups

Sixty patients are randomly divided into two intervention groups (n=30 cases). In the intervention group 1, the treatment will be performed by conventional ponseti method and in the intervention group 2, the treatment will be performed by accelerated ponseti method.

Main outcome variables

Required times for plastering in order to abduction the foot to 70° in relation to the leg and skin complications such as severe erythema, ulcer, skin necrosis and severe maceration are evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180924041120N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Hamed Bahrami Yarahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Therapeutic Results of Conventional and Accelerated Ponseti Method in Children with Idiopathic Clubfoot

Public title

Comparison the Therapeutic Results of Conventional and Accelerated Ponseti Method in Children with Idiopathic Clubfoot

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Idiopathic Clubfoot Age <1 year

Exclusion criteria:

The syndromic and complex club foot The relapsed club foot History of any surgical or non-surgical procedure in other centers

Age

To 1 year old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 60

More than 1 sample in each individual

Number of samples in each individual: 2

Two feet in a child

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random allocation rule: First the sample size was calculated. Then, the subjects (n=60) are randomly assigned into two groups of conventional and accelerated Ponseti method (each 30). In the random assignment, 28 cards are assigned to intervention and 28 to control group. The cards are randomly and without replacement removed from the box and the sequence is recorded.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyses are blind to the groups allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan Blvd., Research deputy, Ahvaz Jundishapur University Of Medical Sciences

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Province

Khouzestan

Postal code

6135715794

Approval date

2017-11-08, 1396/08/17

Ethics committee reference number

IR.AJUMS.REC.1396.1052

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

club foot

ICD-10 code

Q66.8

ICD-10 code description

Other congenital deformities of feet

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

Rate of deformity correction

Timepoint

When the foot could be abducted to 70° in relation to the leg

Method of measurement

According to the Dimeglio and Pirani scoring systems

2**Description**

Duration of treatment

Timepoint

The interval between the beginning and the completion of plastering

Method of measurement

Number of weeks

3**Description**

Skin complications

Timepoint

The interval between the beginning and the completion of plastering

Method of measurement

Weekly examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The treatment will be performed by conventional ponseti method. The plasters are replaced weekly on a fixed day and continued since the foot could be abducted to 70° in relation to the leg.

Category

Treatment - Other

2

Description

Intervention group 2: The treatment will be performed by accelerated ponseti method. The plasters are replaced two times in a week on fixed days and continued since the foot could be abducted to 70° in relation to the leg.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Hamidreza Arti

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Mohammad Badavi, PhD

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Grant name

Grant code / Reference number

96172

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hamed Bahrami Yarahmadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available