

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Outcome investigation of congenital trigger thumb release by percutaneous surgery in children: a before-after clinical trial

Protocol summary

Summary

Objectives: To assess outcome of congenital trigger thumb release by percutaneous surgery in children.
Design: A before-after clinical trial. **Setting and conduct:** The eligible children with congenital trigger thumb who will refer to Besat Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 1 to 10 years; congenital trigger thumb. **Exclusion criteria:** Hand tendon disorders. **Intervention group:** Congenital trigger thumb release percutaneous surgery. **Control group:** In comparison with before intervention. **Primary outcome:** Assessing the thumb movement 1 and 2 months after surgery through physical examination. **Secondary outcome:** Examining side effects include bowing tendon or digital nerve damage. **Randomization:** This is a before after trial without randomization. **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706259014N171**

Registration date: **2017-06-26, 1396/04/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcome investigation of congenital trigger thumb release by percutaneous surgery in children: a before-after clinical trial

Public title

Outcome investigation of congenital trigger thumb release by percutaneous surgery in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 1 to 10 years; congenital trigger thumb. Exclusion criteria: Hand tendon disorders.

Age

From **1 year** old to **10 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Randomization: This is a before after trial without randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.UMSHA.REC.1396.250

Health conditions studied

1

Description of health condition studied

Trigger thumb

ICD-10 code

Q74.0

ICD-10 code description

Other congenital malformations of upper limb

Primary outcomes

1

Description

Assessing the thumb movement

Timepoint

1 and 2 months after surgery

Method of measurement

through physical examination

Secondary outcomes

1

Description

Examining side effects include bowing tendon or digital nerve damage

Timepoint

1 and 2 months after surgery

Method of measurement

through physical examination

Intervention groups

1

Description

Intervention group: Congenital trigger thumb release percutaneous surgery.

Category

Treatment - Surgery

2

Description

Control group: In comparison with before intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Yoosef Ali Aghabozorgi

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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Hamadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research and Technology, Hamadan 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

Person responsible for general inquiries

Contact
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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