Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
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
Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Yoosef Ali Aghabozorgi
Position
Resident of Orthopedic
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
rezvan.azimi95@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Yoosef Ali Aghabozorgi
Position
Resident of Orthopedic
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
rezvan.azimi95@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
poorolajal@umsha.ac.ir
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