Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the repair process of thumb flexor tendons after Botox injection in the thumb flexor muscles

Protocol summary

Study aim
Determining the effect of Botox injection on the repair process of thumb flexor tendons

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. Balanced block randomized method is used for randomization.

Settings and conduct
This is a clinical trial study on deep flexor tendon of the thumb which will be performed on 100 people who are between 15 and 50 years old by the Kessler method in Shahid Rajaei Hospital, Qazvin province. One hour before surgery, Botox will be injected into the intervention group, after the surgery, a plaster cast is performed for 4 weeks, and after removing the plaster, physiotherapy is performed for 3 months. It is a double-blind type. Based on what is mentioned in the consent form, patients will be blind. Since the writing of the article will be done by the surgeon, so blinding will not be done him. Nurses and especially physiotherapists are blind to the intervention.

Participants/Inclusion and exclusion criteria
Patients aged 15 to 50 who have acute damage to the deep flexor tendons of the thumb and refer to the surgical clinic of Shahid Rajaei Hospital in Qazvin. Provide written consent to enter the study

Intervention groups
Control group: After the surgery, control group is casted for 4 weeks, after removing the cast, physiotherapy will be done for 3 months in the control group. Intervention group: One hour before the start of the reconstructive surgery, between 50 and 100 units of botulism toxin along with 10 ml of normal saline are injected into the flexor pollicis longus (FDL) muscle. Injected botulism is produced by Diston brand of Imen Vaccine pharmaceutical company.After surgery, intervention group is casted for 4 weeks. After removing the cast, physiotherapy will be done for 3 months in intervention group.

Main outcome variables
Evaluation of joint movement limitation in each group.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220723055523N1**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**
Update count: **0**

Registration date
2022-08-16, 1401/05/25

Registrant information

Name
Behzad Afzali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5254 6945

Email address
drbehzadaf@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the repair process of thumb flexor tendons after Botox injection in the thumb flexor muscles

Public title
Evaluation of the repair process of thumb flexor tendons after Botox injection in the thumb flexor muscles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 15 to 50 who have acute damage to the deep flexor tendons of the thumb and refer to the surgical clinic of Shahid Rajaei Hospital in Qazvin. Provide written consent to enter the study
Exclusion criteria:
Patients who have simultaneous damage to hand extensor tendons. Patients who have simultaneous damage in two flexor levels of the hand. Patients who have simultaneous bone fractures in the affected limb. Patients who have simultaneous nerve damage in the affected limb.
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are assigned randomly in a double-blind manner in the control or intervention groups based on the Balanced Block Randomization method into two groups A and B in blocks AABB-BBAA- ABAB-BABA-ABBA-BAAB which are 4 blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind type of experiment that will be blind for the people participating in the study. In the consent form to participate in the study, it is written for the patient that his presence does not necessarily mean intervention but may be included in the control group. The main investigator of the study in this trial will not be blind because he will be the final evaluator of the results between the two groups. Since the writing of the article will be done by the main researcher, who is responsible for the project and the analysis of the results at the end, blinding will not be done for him. In addition, considering that this is a study that takes place during hand tendon surgery, it is practically not possible to keep the intervention blind for the surgeon, although the nurses and especially the physiotherapist will be blind to the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Maveddat Alley, Shahid Beheshti Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2021-07-18, 1400/04/27
Ethics committee reference number
1400.175.IR.QUMS.REC

Health conditions studied

1

Description of health condition studied
Thumb flexor tendon injury
ICD-10 code
M66.3
ICD-10 code description
Spontaneous rupture of flexor tendons

Primary outcomes

1

Description
Evaluation of joint movement limitation in each group
Timepoint
3 months after surgery
Method of measurement
Buck-Gramcko method

Secondary outcomes

1

Description
Evaluation of tendon re-rupture
Timepoint

3 months after surgery

Method of measurement

Magnetic resonance imaging (MRI)

2

Description

Evaluation of the side-effects of Botulism injection

Timepoint

3 months after surgery

Method of measurement

Asking patients and evaluating its performance by the surgeon

Intervention groups

1

Description

Control group: after the surgery, casting is done for 4 weeks, after removing the cast, active movements and physiotherapy are done for 3 months in the control group.

Category

Treatment - Surgery

2

Description

Intervention group: One hour before the start of the reconstructive surgery, between 50 and 100 units of botulism toxin along with 10 ml of normal saline are injected into the flexor pollicis longus (FDL) muscle. Injected botulism is produced by Diston brand of Imen Vaccine pharmaceutical company.After surgery, intervention group is casted for 4 weeks. After removing the cast, active movements and physiotherapy are done for 3 months in intervention group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

Behzad Afzali

Street address

Shahid Safdari Alley, Padegan Ave, Qazvin

City

Qazvin

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3413996134

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mahdi Mirhashemi

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Behzad Afzali

Position

Surgical resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Soroush

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Surgical resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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 variables and total potential data can be shared after people are identifiable

When the data will become available and for how long

start access period 6 months after printing results

To whom data/document is available

It will be available to researchers working in academic institutions.

Under which criteria data/document could be used

The data can be reviewed and used to improve clinical conditions and maintain patient health and perform meta-analyzes.

From where data/document is obtainable

They can request the author's email or from the research center or university.

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

Apply by email or post to Qazvin University of Medical Sciences.

Comments