

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of percutaneous needle on A1 poly release in trigger finger

Protocol summary

Study aim

Determining the effect of the percutaneous needle method on the amount of A1 release in trigger finger

Design

This study consists of two groups of 10 people who are assigned to one of the intervention groups which is to perform treatment with pink or green needle by simple random method and removing the type of intervention (code number 1 or 2) from inside the envelope. The study is double-blind, and the patients and the evaluator are unaware of the type of intervention

Settings and conduct

The study was conducted in Hazrat Fatemeh Hospital in Tehran, and after being assigned to the desired group, the patient was operated percutaneously with one of the types of needles, and after that, all patients underwent open surgery to determine the degree of tendon and vascular damage and the degree of release. find awareness

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Trigger finger, People between 18 and 60 years old
Exclusion criteria: Diabetics, People with previous reconstructive surgery

Intervention groups

The first group (intervention) includes people whose A1 monetary release is treated with the percutaneous needle method with a pink needle, and the second group (control) includes people whose A1 monetary release is treated with the same method but with a green needle

Main outcome variables

The amount of poly release, The amount of tendon damage, The amount of vascular damage, The amount of tissue damage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057488N1**

Registration date: **2023-02-26, 1401/12/07**

Registration timing: **prospective**

Last update: **2023-02-26, 1401/12/07**

Update count: **0**

Registration date

2023-02-26, 1401/12/07

Registrant information

Name

Afsane Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

dr.afsanehbagheri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of percutaneous needle on A1 poly release in trigger finger

Public title

Investigating the effect of percutaneous needle method

in the repair of trigger finger

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People between 18 and 60 years old Having a Trigger finger
Exclusion criteria:
Diabetic people No previous reconstructive surgery

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
We have 10 numbers of code number 1 and 10 numbers of code number 2, which we put in an envelope and draw lots for each patient before the operation, using a simple random method. Code number one is related to treatment with pink needle and code number two is green needle

Blinding (investigator's opinion)
Double blinded

Blinding description
We throw 20 pieces of paper into the envelope by a simple random method. We write code number 1 on 10 numbers and code number 2 on the other 10 numbers, and before the operation we take out a paper from the envelope, if the code number is one, the treatment will be done with a pink needle, and if it is number two, the treatment will be done with a green needle. became

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Hemmad highway. Iran University of Medical Sciences

City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.IUMS.FMD.REC.1401.496

Health conditions studied

1

Description of health condition studied
Trigger finger
ICD-10 code
M65.3
ICD-10 code description
Trigger finger

Primary outcomes

1

Description
The amount of release of A1 poly
Timepoint
Immediately after surgery
Method of measurement
Observation in open surgery method

Secondary outcomes

1

Description
Tendon damage
Timepoint
Immediately after surgery
Method of measurement
Observation in open surgery method

2

Description
Vascular damage
Timepoint
Immediately after surgery
Method of measurement
Observation in open surgery method

3

Description
Tissue damage
Timepoint
Immediately after surgery
Method of measurement
Observation in open surgery method

Intervention groups

1

Description

Intervention group: A1 poly release by entering the poly at an angle of 45 degrees from the surface of the hand with a pink needle and then opening the skin of the hand and observing the amount of release and damage

Category

Treatment - Surgery

2

Description

Control group: A1 poly release by entering the poly at an angle of 45 degrees from the surface of the hand with a green needle and then opening the skin of the hand and observing the amount of release and damage

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Fatemeh Hospital

Full name of responsible person

Mohamadreza Akhondinasab

Street address

Seyed Jamalodin Asadabadi St.

City

Tehran

Province

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Postal code

1433933111

Phone

+98 21 8871 7272

Email

akhondinasab@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Hemmad highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 8670 2504

Email

keyvani.h@iums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Hazrate Fatemeh Hospital

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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Bagheri

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohamadreza Akhondinasab

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic and Reconstructive Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The written informed consent form will be provided to the participants before the procedure, and then it will be included in the thesis. We have also published it in the researcher system. The data of the study also includes the results of the variables, including the amount of Poly release, the amount of vascular, tendon and tissue damage that is included in the thesis report

When the data will become available and for how long

The consent form will be placed in the attachments section after the thesis is printed. Also, the data of the participants is included in the thesis

To whom data/document is available

All people who have access to the full text of the thesis

Under which criteria data/document could be used

It can be modeled in similar studies

From where data/document is obtainable

Email to the general supervisor of the thesis Dr. Afsaneh Bagheri dr.afsanehbagheri@gmail.com

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

After sending the email to the general supervisor, the thesis can be received within 1 week

Comments