

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Therapeutic responses to Subcutaneous versus Intra-sheath sonographically guided corticosteroid injection in the management of Trigger Finger

#### Protocol summary

##### Summary

(1) Objectives: This study seeks to evaluate Therapeutic responses to Subcutaneous versus Intra-sheath sonographically guided corticosteroid injection in the management of Trigger Finger. (2) Design: triple blinded randomized controlled trial. (3) Setting and conduct: after randomization using random block system, 1 c.c of "Methyl-prednisolon acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% will be injected in all fingers at the level of A1 pulley under sonographic guidance. Injection will execute intra-sheath in control group and subcutaneous in intervention group. (4) Participants including major eligibility criteria: All patients with three symptoms of pain and tenderness at the position of A1 pulley, feeling pain and discomfort when flexing and extending finger, and nodule palpation. Exclusion criteria: Any kind of concomitant local Tenosynovitis such as DeQuervain Disease, carpal tunnel syndrome, and Dupuytren's Contracture; clinical doubt to other diseases with similar symptoms and their affirmation in executed investigations; any history of local injection of corticosteroid; and any associated medical conditions. (5) Intervention: Intervention group: subcutaneous injection, Control group: Intra-sheath injection. (6) Main outcome measures: Measuring alteration of Quinnell's grade.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202187274N3**

Registration date: **2012-04-04, 1391/01/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-04-04, 1391/01/16

##### Registrant information

###### Name

Mohsen Mardani Kivi

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1321 1470

###### Email address

mardani@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2012-03-05, 1390/12/15

##### Expected recruitment end date

2013-09-05, 1392/06/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic responses to Subcutaneous versus Intra-sheath sonographically guided corticosteroid injection in the management of Trigger Finger

##### Public title

Therapeutic responses to Subcutaneous versus Intra-sheath sonographically guided corticosteroid injection in

the management of Trigger Finger

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

Inclusion Criteria: having three symptoms of pain and tenderness at the position of A1 pulley, feeling pain and discomfort when flexing and extending finger, and nodule palpation. Exclusion Criteria: Any kind of concomitant local Tenosynovitis such as DeQuervain Disease, carpal tunnel syndrome, and Dupuytren's Contracture; clinical doubt to other diseases with similar symptoms and their affirmation in executed investigations; any history of local injection of corticosteroid; and any associated medical conditions such as diabetes melitus, rheumatoid arthritis and hypothyroidism.

## **Age**

From **14 years** old to **149 years** old

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **166**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Triple blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee, Guilan University of Medical Sciences

##### **Street address**

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

##### **City**

Rasht

##### **Postal code**

#### **Approval date**

2012-01-11, 1390/10/21

#### **Ethics committee reference number**

1901130512

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Trigger Finger

#### **ICD-10 code**

M65.3

#### **ICD-10 code description**

Trigger finger, Nodular tendinous disease

## **Primary outcomes**

### 1

#### **Description**

Therapeutic response (Decrease in Quinnell's grade)

#### **Timepoint**

Before first injection, 3 and 6 weeks, 3 and 6 months and 1 year after first injection

#### **Method of measurement**

Quinnell's grade

## **Secondary outcomes**

### 1

#### **Description**

Reinjection

#### **Timepoint**

3 and 6 weeks, 3 and 6 months and 1 year after first injection

#### **Method of measurement**

Number

### 2

#### **Description**

Open Surgery

#### **Timepoint**

6 weeks, 3 and 6 months and 1 year after first injection

#### **Method of measurement**

Number

## **Intervention groups**

### 1

#### **Description**

Intervention group: 1 c.c of "Methyl-prednisolon acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% will be injected subcutaneously under sonographic guidance.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: 1 c.c of "Methyl-prednisolon acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% will be injected intra-sheath under sonographic guidance.

#### **Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Imam-Reza Clinic of Poursina Hospital

**Full name of responsible person**

Mohsen Mardani Kivi MD.

**Street address**

Imam-Reza clinic, Poursina hospital, Parastar avenue

**City**

Rasht

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Guilan University of Medical Science

**Full name of responsible person**

Prof. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science

**Street address**

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

**City**

Rasht

**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, Guilan University of Medical Science

**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**

Guilan University of Medical Science

**Full name of responsible person**

Mohsen Mardani Kivi MD.

**Position**

Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*