

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

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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

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 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