Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of Ibuprofen therapy effect in prevent of tissue adhesion after flexor tendon repair in zone two of hand

Protocol summary

Summary

Peritendinous adhesions after repair of an injury to the digital flexor tendons are a major problem in hand surgery. Nonsteroidal anti inflammatory drugs therapy may affect tendon healing and the development of peritendinous adhesions. Aim of this study is evaluation of Ibuprofen effect in patients function and prevent of tissue adhesions after flexor tendon surgical repair. In this clinical trial study, 60 patients with sharp laceration in zone two of the hand that need to repair of flexor tendon will be evaluated. Patients divided randomly in two parallel groups (30 patients in each group) and matched with together according to age, sex and size of laceration. Patients in control group will receive placebo in same shape and size. In intervention group patients will receive Ibuprofen (2400mg per day). Patients will be excluded if they had previous flexor tendons injury or gastrointestinal disease. Tendon adhesion and flexor tendons function will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301189857N2**
Registration date: **2013-02-14, 1391/11/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-14, 1391/11/26

Registrant information

Name

Ali Tabrizi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-01-19, 1391/10/30

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ibuprofen therapy effect in prevent of tissue adhesion after flexor tendon repair in zone two of hand

Public title

Evaluation of medical therapy in improvement of hand tendons function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 60 years. Laceration in vollar hand in zone two. Exclusion criteria: patients with cardiovascular or gastrointestinal disease, patients with previous flexor tendons injury or surgery

Age

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

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In this clinical trial study, patients will be divided in two parallel groups with simple random sampling. Patients will be received ibuprofen in intervention group and placebo in control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Tabriz University of Medical Sciences
Street address
Golgasht Ave, Tabriz Medical Faculty
City
Tabriz
Postal code
Approval date
2012-12-26, 1391/10/06
Ethics committee reference number
25/91/ب

Health conditions studied

1

Description of health condition studied
Tendon Injury
ICD-10 code
M65-M68
ICD-10 code description
Other contracture of tendon

Primary outcomes

1

Description
Flexor tendons function
Timepoint
Each two weeks
Method of measurement
Measurement of involved finger motion

2

Description
Tendon rupture
Timepoint
End of follow up
Method of measurement
Assay tendon motion clinically

Secondary outcomes

1

Description
Tissue adhesion
Timepoint
End of follow up
Method of measurement
By full moving the fingers and hands

2

Description
The need for further surgery
Timepoint
End of study
Method of measurement
Limitation of motion

Intervention groups

1

Description
Patients in interventional group will be received ibuprofen 2400 mg produced by Zahravy pharmaceutical companies in every day for a month.
Category
Treatment - Drugs

2

Description
Patients in control group will be received placebo in same shape and size similar to intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohda Educational Hospital
Full name of responsible person
Alireza Rouhani
Street address

Golshahr Ave, Shohada Educational Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Sadeghpour

Street address

Shohada Educational Hospital

City

Tabriz

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 Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Tabrizi

Position

MD\Orthopedic resident

Other areas of specialty/work

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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