Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the Effect of Betamethasone and Ketorolac Injection on Treatment of De Quervain`s Tenosynovitis in Diabetic Patients

Protocol summary

Study aim
Comparison of the effect of local injection of betamethasone and ketorolac in treatment of patients with De Quervain`s tenosynovitis and diabetes .

Design
Clinical trial with two parallel groups, double-blind, randomized, phase 4 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct
We decided to compare the effectiveness of ketorolac as a non-steroidal anti-inflammatory drug versus betamethasone as a steroidal anti-inflammatory drug. Therefore, After visiting in the specialized orthopedic clinic and obtaining informed consent, Ketorolac or betamethasone will inject in a double-blind manner (doctor and patient) and its results in pain control will be studied and compared in two groups. Doctor's informed assistant will prepare the syringe containing the medicine and record patients' information for follow-up.

Participants/Inclusion and exclusion criteria
Patients with De Quervain`s tenosynovitis and controlled type 2 diabetes over 18 years of age can enter the study. Pregnant women, patients who have a history of local corticosteroid injection or previous surgery and fracture in the same wrist will not be included in the study.

Intervention groups
In this study, patients are randomly divided into two groups treated with betamethasone injection and ketorolac injection.

Main outcome variables
Investigating the effectiveness of ketorolac injection and comparing it with betamethasone in controlling the pain of De Quervain's tenosynovitis in diabetic patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220611055139N1**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**

Registration date
2022-08-19, 1401/05/28

Registrant information

Name
Mehdi Zare
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-10, 1401/05/19

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effect of Betamethasone and Ketorolac Injection on Treatment of De Quervain`s Tenosynovitis in Diabetic Patients

Public title

Comparing the Effect of Betamethasone and Ketorolac Injection on Treatment of De Quervain`s Tenosynovitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

De Quervains Tenosynovitis Patients Diabetes mellitus Type 2 Patients Persons more than 18 yo ages

Exclusion criteria:

History of Allergic Reaction to Lidocaine ،Ketorolac (and other NSAIDs) ،Aspirin and Betamethasone History of Corticosteroids Injection in past 3 months History of surgery due to De Quervain`s Tenosynovitis in same wrist Pregnant ،Breastfeeding period and Patient with Gestational Diabetes Skin complications such as wounds, eczema or rash at the injection site Active infection at the injection site History of acute wrist trauma, history of wrist fracture, rheumatoid arthritis, uncontrolled diabetes Patients with type 1 diabetes

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size of 60 patients was divided into 10 blocks with different random sizes of 4, 6 and 8 (3 blocks of 4, 4 blocks of 6, 3 blocks of 8) using the Permuted block randomization method by Excel computer software. Then the people of each block are randomly and equally divided into two groups under treatment A or B, and finally 30 patients will be treated with A and 30 patients will be treated with B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering the proven effectiveness of both betamethasone and ketorolac in the treatment of De Quervains patients, in a randomized and double-blind manner, neither the treating doctor nor the patient knows about the drug in the syringe, and the preparation and recording of information is the responsibility of the physician's assistant who It is aware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Imam Khomeini Hospital, Ershad Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.UMSU.REC.1401.105

Health conditions studied

1

Description of health condition studied

De Quervains tenosynovitis

ICD-10 code

M65.4

ICD-10 code description

Radial styloid tenosynovitis [de Quervain]

Primary outcomes

1

Description

The amount of pain described by the patient

Timepoint

first session, 6 week, 3 months ,6 months after injection

Method of measurement

Visual Analogue Scale Score

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Local injection of 1 cc betamthasone (1cc/4 mg-Darou Pakhsh Pharmaceutical Manufacturing Company) with 1 cc Lidocaine 2% approximately 2 cm proximal to radius styloid، in first extensor tendons compartment of wrist

Category

Treatment - Drugs

2

Description
Second Intervention group: Local injection of 1 cc ketorolac (1cc/30 mg-Darou Pakhsh Pharmaceutical Manufacturing Company) with 1 cc Lidocaine 2% approximately 2 cm proximal to radius styloid، in first extensor tendons compartment of wrist
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
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Imam Khomeini hospital of Urmia
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Sponsors / Funding sources

1

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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
Oroumia 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
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Full name of responsible person
Mehdi Zare
Position
Resident of Orthopaedics surgery
Latest degree
Medical doctor
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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available