

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 935 950 2079

###### Email address

zare.mehdi8911215083@gmail.com

##### 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**

**Name of recruitment center**

Imam Khomeini hospital of Urmia

**Full name of responsible person**

Mehdi Zare

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Imam Khomeini hospital, Ershad Blvd.

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Zare.mehdi8911215083@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

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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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Mehdi Zare

**Position**

Resident of Orthopaedics surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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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