

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Clinical trial of comparison of needle stick pain due to digital block in finger traumatic patients with and without using an ice in site of damage.

#### Protocol summary

##### Summary

This is a randomized clinical trial, non-blinded study that has been designed for 100 patients with traumatic finger injuries who need some procedures on their fingers. It sets up at Imam Khomeini and Sina hospitals during 1394 until 1395. One hundred patients with traumatic finger injury requiring digital nerve block are randomly divided to two control and case groups. In the case group, injured fingers are thoroughly covered by ice for 6 minutes following by needle insertion. The procedure is conducted with no ice application in the control group. Afterwards, the injured finger is anesthetized using Lidocaine. Numeric Rating Scale (NRS) is records after ice application, during needling and the time of injection. This scale has range of 0-10. Results will be published in mean and standard deviation. In addition, satisfaction questionnaire will be filled after procedure completion.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017010731807N1**

Registration date: **2017-09-23, 1396/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-23, 1396/07/01

##### Registrant information

##### Name

Fatemeh Rasooli

##### Name of organization / entity

Sina Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8500

##### Email address

f-rasooli@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2016-02-19, 1394/11/30

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of comparison of needle stick pain due to digital block in finger traumatic patients with and without using an ice in site of damage.

##### Public title

Ice effect on pain reduction due to needle insertion during digital block

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Informed consent (according standard consent), age range: 16-50 years old, fingers trauma which need medical procedures or extra assessment under local anesthesia. Exclusion criteria: Pregnant women, history of reaction to the local anesthetic agents, history of sensitivity to cold, unable to make communication, phobia, opium using during 6 hours before admission, emergent situations, unstable medically patients.

##### Age

From **16 years** old to **50 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Type of randomization: Block Randomize

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Central building of Tehran University of Medical Science, Ghods Ave, Keshavarz Blvd, Tehran

##### City

Tehran

##### Postal code

1419732171

#### Approval date

2016-02-16, 1394/11/27

#### Ethics committee reference number

IR.TUMS.REC.1394.1986

## Health conditions studied

### 1

#### Description of health condition studied

Finger trauma

#### ICD-10 code

M65, M66,

#### ICD-10 code description

Disorders of synovium and tendon, Other soft tissue disorders

## Primary outcomes

### 1

#### Description

Pain due to needle stick of digital block

#### Timepoint

On admission, after using ice, time of skin needling, during injection.

#### Method of measurement

NRS Questionnaire

## Secondary outcomes

### 1

#### Description

Patient satisfaction

#### Timepoint

At the end of procedure

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Case group: There are 50 patients in this group. Injured finger is covered by ice for 6 minutes before needling. Afterwards, finger is anesthetized by 3 milliliters lidocaine.

#### Category

Treatment - Other

### 2

#### Description

Control group: There are 50 patients in this group. Finger is anesthetized by using Lidocaine, with no ice application.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Behzad Simiari

##### Street address

Tehran, Keshavarz Boulevard, Imam khomeini Hospital

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Sina Hospital

**Full name of responsible person**

Fatemeh Rasooli

**Street address**

Hassanabad Square, Imam Khomeini Street, Sina Hospital

**City**

Tehran

**Fax****Email**

f-rasooli@tums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Tehran University of Medical Sciences

**Position**

Vice chancellor for research, Tehran University of Medical Sciences

**Other areas of specialty/work****Street address**

Qods Street, Keshavarz Boulevard, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8163 3698

**Fax****Email**

tums\_edu@tums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Tehran University of Medical Sciences

**Street address**

Vice chancellor for research, Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.

**City**

Tehran

**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, Tehran 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**

Sina Hospital

**Full name of responsible person**

Fatemeh Rasooli

**Position**

Assistant Professor of Emergency Medicine

**Other areas of specialty/work****Street address**

Hassanabad Square, Imam Khomeini Street

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Person responsible for updating data****Contact****Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Fatemeh Rasooli

**Position**

Emergency Medicine Specialist

**Other areas of specialty/work****Street address**

Hassanabad Square, Imam Khomeini Street

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Fax**

+98 66348553

**Email**

hosp\_sina@sina.tums.ac.ir

**Web page address**

http://sinahospital.tums.ac.ir/

**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*