

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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