

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The Effect of using Local Finger Cold on Pain caused by Glucometer Needle, Blood Glucose Concentration and Satisfaction in Patients with Diabetes

#### Protocol summary

##### Study aim

Determining the effect of using local finger cold on the pain caused by the glucometer needle, blood sugar level and satisfaction of patients with diabetes.

##### Design

A controlled, parallel-group, unblinded, non-randomized, phase 2 clinical trial on 40 patients.

##### Settings and conduct

Patients with type 2 diabetes admitted to hospitals affiliated to Shahid Beheshti University of Medical Sciences, where the finger of one hand of each patient is considered as the intervention group and the finger of the other hand as the control group and without blinding have been.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type 2 diabetes; full consciousness; familiarity with the Persian language; lack of sensory and mental disorders; No treatment with sedatives  
Exit criteria: having any pain; lack of cooperation and consent; sensitivity to karyotherapy; having a skin wound at the cryotherapy site; presence of peripheral neuropathy; Use of painkillers in the previous 24 hours

##### Intervention groups

In the intervention group, first, a cube-shaped piece of ice was placed in a nylon freezer and placed on the desired finger for the needle to enter, and the patient was asked to rub for 30-45 seconds before the needle was inserted. Then the needle was inserted and immediately the pain level of the patients was checked. A needle was placed on the finger of the other hand without cryotherapy, and the patient's pain and blood sugar levels were immediately recorded.

##### Main outcome variables

The level of blood sugar, the level of pain caused by the glucometer needle, the level of satisfaction of patients with type 2 diabetes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230724058906N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

##### Registration date

2023-09-02, 1402/06/11

##### Registrant information

##### Name

Zahra Khorrami khorram abadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 697 0429

##### Email address

zahrakhorrami77@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

2023-01-05, 1401/10/15

##### Actual recruitment end date

2023-02-04, 1401/11/15

##### Trial completion date

2023-02-04, 1401/11/15

## Scientific title

The Effect of using Local Finger Cold on Pain caused by Glucometer Needle, Blood Glucose Concentration and Satisfaction in Patients with Diabetes

## Public title

The Effect of Cryotherapy on Pain Caused by Glucometer

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with type 2 diabetes who are confirmed by a specialist doctor Full alertness Familiarity with Persian language Absence of vision and hearing impairment and active mental illness No treatment with sedatives (according to the patient himself) and painkillers in the last 24 hours

### Exclusion criteria:

Having any noticeable pain before the needle is inserted Having obvious behavioral problems or lack of cooperation and consent to carry out interventions The presence of any sensitivity to cryotherapy or those suffering from Raynaud's syndrome or sickle cell anemia Having a skin wound at the cryotherapy site Absence of peripheral neuropathy in patients History of using painkillers, anesthesia and lidocaine and similar compounds in the previous 24 hours

## Age

From **30 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Examining the blood sugar and the amount of pain caused by the glucometer needle in the finger of two different hands of the patient, and the finger of one hand as the intervention group and the finger of the other hand as the control group.

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Examining the blood sugar and the amount of pain caused by the glucometer needle in the finger of two different hands of the patient, and the finger of one hand as the intervention group and the finger of the other hand as the control group.

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Ethics committee of Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Vali Asr St., intersection of Ayat Ah... Hashemi Rafsanjani Highway, in front of Shahid Rajaei Heart Hospital.

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835119

#### Approval date

2022-09-06, 1401/06/15

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.124

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

The pain score caused by the glucometer needle with a visual scale

#### Timepoint

Before and after cryotherapy

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Amount of pain and blood sugar level based on the number displayed by the glucometer.

#### Timepoint

Before and after cryotherapy  
**Method of measurement**  
The number displayed by the glucometer.

## Intervention groups

### 1

#### Description

Intervention group: In the cryotherapy method, first, a cube-shaped piece of ice is placed in a nylon freezer and placed on the desired finger for the needle to enter, and the patient is asked to rub the said place for 30 seconds before the needle enters. Then, the entry site is well disinfected and the needle is inserted, and the pain level of the patients is immediately assessed using the visual pain criterion.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohada Tajrish hospital

##### Full name of responsible person

Zahra Khorrami khorram abadi

##### Street address

Shohadaye Tajrish Educational Medical Center,  
Shahadari St., Tajrish Square.

##### City

Tehran

##### Province

Tehran

##### Postal code

1989934148

##### Phone

+98 21 2271 8000

##### Email

pr-shohada@sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Imam Hussein hospital

##### Full name of responsible person

Zahra Khorrami khorram abadi

##### Street address

Imam Hossein Medical Research Training Center,  
Shahid Madani St.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

##### Phone

+98 21 7343 0000

##### Email

info@sbmu.ac.ir

### 3

#### Recruitment center

##### Name of recruitment center

Ayatollah Taleghani hospital hospital

##### Full name of responsible person

Zahra Khorrami khorram abadi

##### Street address

Ayatollah Taleghani Hospital, Yemen St., Shahid Arabi  
St., Shahid Chamran Highway.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

##### Phone

+98 21 2303 1100

##### Email

info@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Vice President of Research and Technology of Shahid  
Beheshti University of Medical Sciences

##### Street address

Faculty of Nursing and Midwifery, Shahid Beheshti  
University of Medical Sciences, Valiasr Street, Niayesh  
highway cross, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835119

##### Phone

+98 21 8865 5366

##### Email

zahrakhorrami77@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Zahra Khorrami khorram abadi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Valiasr Street, Niayesh highway cross  
**City**  
Tehran  
**Province**  
Tehran  
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1996835119  
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+98 21 8865 5366  
**Email**  
zahrakhorrami77@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Zahra Khorrami khorram abadi  
**Position**  
Student  
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Tehran  
**Province**  
Tehran  
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**Phone**  
+98 21 8865 5366  
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zahrakhorrami77@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Zahra Khorrami khorram abadi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Valiasr Street, Niayesh highway cross, Tehran,  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1996835119  
**Phone**  
+98 21 8865 5366  
**Email**  
zahrakhorrami77@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

### Title and more details about the data/document

The individual data of the participants and the informed consent form in the study can be shared after de-identification.

### When the data will become available and for how long

The access period starts 6 months after the results are published

### To whom data/document is available

All those interested in the field of medical sciences and pain control in patients with diabetes

### Under which criteria data/document could be used

The use and analysis of the data of this study is allowed if it is done ethically, and people can request the use of the data by sending an email or a letter to the responsible author.

### From where data/document is obtainable

Zahra Khorrami Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Valiasr Street, Niayesh highway cross, Tehran, Iran. Tel: 09136970429  
Email: zahrakhorrami77@gmail.com

**What processes are involved for a request to access data/document**

The applicant can request the use of the information by sending an email to the responsible author at zahrakhorrami77@gmail.com and I will provide the information to the applicant for a maximum of 7 working days after receiving the email.

**Comments**