

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.

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1989934148

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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.

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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
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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.

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1996835119

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+98 21 8865 5366

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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Student
Latest degree
Bachelor
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Person responsible for updating data

Contact

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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