

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Review and compare of effect of local application Peppermint with Cold compress on the severity of pain due to the entry of needle into the arteriovenous fistula in dialysis patients

Protocol summary

Study aim

The effect of topical application of Peppermint and Cold compress on the severity of needle pain in arteriovenous fistula in dialysis patients

Design

Clinical trial with control group with parallel groups, randomized without blinding.

Settings and conduct

Samples were selected from patients in dialysis ward of all hospitals of Shahrud city by randomized block design, then participants were divided into 3 groups: peppermint (intervention A), cold compress (intervention B) and control group (C). After obtaining informed consent from patients, group (A) was applied 10 minutes before venipuncture 1 ml of peppermint gel with a surface area of 5 x 5 cm. In group B Ice bag placed on the skin five minutes before the vessel is occluded. In group C, no action is taken. All patients were disinfected 30 min before venipuncture. Immediately after venipuncture, patients will be evaluated and recorded using the VAS Visual Anxiety Rating Scale.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 18 to 65 years, Having complete vigilance Hemodialysis patients undergoing dialysis at least 2 sessions per week. Patients who have at least 3 months past their fistula. Non-arrival conditions: Patient's Verbal and Mental Disabilities Acute pain for any reason. Use painkiller 12 hours before venipuncture A history of allergy to Peppermint. Drug addiction and painkillers The presence of damaged skin at the desired position

Intervention groups

For the group (A), the group intervention 20 minutes before the veinpuncture of 5 mL of Peppermint Ointment With the brand name MentoraFort by Applicator (5mL) took from within container from the dish to an area of 5 at 5 cm on used the point where the fistula. For the

intervention group(B), the ice bag is placed on the skin 5 minutes before venipuncture. No action is taken for group C, which is the control group.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044608N2**

Registration date: **2019-11-30, 1398/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name

Bitra Koushki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 7424

Email address

koushki@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Review and compare of effect of local application Peppermint with Cold compress on the severity of pain due to the entry of needle into the arteriovenous fistula in dialysis patients

Public title

Review and compare of effect of local application Peppermint with Cold compress on the severity of pain due to the entry of needle into the arteriovenous fistula in dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 to 65 years Having complete vigilance Hemodialysis patients undergoing dialysis at least 2 sessions per week Patients who have at least 3 months past their fistula.

Exclusion criteria:

Patient's Verbal and Mental Disabilities Acute pain for any reason Use painkiller 12 hours before venipuncture A history of allergy to peppermint Drug addiction and painkillers The presence of damaged skin at the desired position

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **99****Randomization (investigator's opinion)**

Randomized

Randomization description

Since the participants will steadily enter into the study and the groups will have equal contributors, the 6-block method would be used for the randomization and its unit is individual. The random assignment sequence is obtained using the software by the methodology consultant. The qualified patient is registered by the first host and the assignment of participants into the groups is also performed by the same person based on the recorded model in the first stage. The random order would be conducted in secret. In detail, 99 packets are provided in the opaque package containing A, B, and C codes. A full informed consent are provided from all participants. The researcher will take the intended envelope in the specified sequence and perform according to the registered group in the envelope.

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 Shahroud University of Medical Sciences

Street address

Shahroud, Haftam Tir Square - Shahroud University of Medical Sciences and Health Services

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.SHMU.REC.1398.074

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes**1****Description**

Pain

Timepoint

Immediately after needle insertion into the arteriovenous fistula

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

for the group (A) 10 minutes before venipuncture, 5 ml of gel Peppermint (Mentorafort brand) in an area of 5 x 5 cm of the fistula will be applied by using an applicator.

Category

Treatment - Drugs

2

Description

For the group (B), the ice bag is placed on the skin 5 minutes before venipuncture.

Category

Treatment - Other

3

Description

Control group: For group C, a routine procedure for venipuncture will be performed

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein , Bahar and Khatamolanbia hospitals

Full name of responsible person

Bitak Koushki

Street address

Shahroud University of Medical Sciences, 7th Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

koushki@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Shahroud University of Medical Sciences, 7th Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

pishgiri@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Bitak Koushki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, 7th Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Phone

+98 23 3239 5054

Email

koushki@shmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Hossein Ebrahimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, 7th Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Phone

+98 23 3239 5054

Email

h_ebrahimi43@yahoo.com

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Phone

+98 23 3239 5054

Email

koushki@shmu.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Unidentifiable patient data are shared.

When the data will become available and for how long

Start access period 1 year after publishing the results

To whom data/document is available

Available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of documentation for medical research is permitted

From where data/document is obtainable

Bitra Koushki koushki90@gmail.com

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

Email your wishes to the email listed above and then receive the information within a week.

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

Shahroud University of Medical Sciences

Full name of responsible person

Bitra Koushki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, 7th Tir Square, Shahroud

City

Shahroud