Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Shahroud 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 veinpunctur of 5 mL ofPeppermint 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

Bita 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
Age
From **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
Bita Koushki
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Sponsors / Funding sources

1

Sponsor
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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
Bita Koushki
Position
Student
Latest degree
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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
Bita Koushki koushkib90@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