Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

The Effect of Ginger on the Severity of Pain due to the entry of needle into the Arteriovenous Fistula in Dialysis Patients

Protocol summary

Study aim

Determination the effect of topical application of ginger on the severity of needle pain in arteriovenous fistula in hemodialysis patients

Design

A randomized controlled trial, with a control group, with parallel groups including 200 dialysis patients. Randomization was performed using the four-way blocking method and concealment in randomization is done by using envelopes in a matte package, with A and B code. The data collector and analyzer not aware of the group allocation.

Settings and conduct

This clinical trial is performed in the dialysis units of Imam Hussein, Bahar and Khatamolanbia hospitals in Shahrood. In this study, pain after needle insertion into arteriovenous fistula was measured after topical application of ginger at the fistula site in hemodialysis patients. Due to the use of ginger ointment which has a smell, it is not possible to blind the participants and only the data collector and analyzer are not aware of the allocation of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemodialysis patients undergoing dialysis for at least 2 sessions per week; patients who have undergone fistula at least 3 months. Exclusion criteria: history of allergy to ginger; use of painkillers 12 hours before venipuncture

Intervention groups

For the intervention group, 20 minutes before the venipuncture 5 ml of ginger ointment, with benzaline 1% brand, made by Notak Far Company of Tehran, is applied to the fistula at 5 x 5 cm. In the control group, venipuncture is performed routinely without any ointment.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044608N1**
Registration date: **2019-10-12, 1398/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-12, 1398/07/20**
Update count: **0**

Registration date

2019-10-12, 1398/07/20

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

2019-10-06, 1398/07/14

Expected recruitment end date

2020-01-04, 1398/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Ginger on the Severity of Pain due to the entry of needle into the Arteriovenous Fistula in Dialysis Patients

Public title

The Effect of Ginger 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 ginger 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: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The 4 - block method is used for randomization, . This is because the participants will gradually study, as well as the number of allocations to each group. The unit of randomization is individual. The random assignment sequence is obtained by the methodology consultant with the software. The qualifying patient is registered by the first host and the participants ' assignment to groups is also performed by the same person on the basis of the recorded model in the first stage. The random order of will is carried out secretly. That is, the number of 200 packets are generated in the Matilda package containing both A and B code. After obtaining conscious satisfaction and identifying that the person is involved in the study, the researcher took the intended envelope in the specified sequence and acted on 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 University of Medical Sciences,7th Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.SHMU.REC.1398.052

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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), the group intervention 20 minutes before the veinpunctur of 5 mL of ginger Ointment With the brand name benzol in 1% Construction of Notekfar company Tehran 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. 30 seconds before the needle is inserted, again disinfect with piodine iodine. The pain of patients will be assessed and recorded immediately

after veinpuncture by another person with VAS scale.

Category

Treatment - Drugs

2

Description

Control group: In control group (B) we use routine method and no solution is used. 30 seconds before the needle is inserted, again disinfect with piodine iodine. In order to prevent differences in the venous pattern and the cause of pain, all patients will be veinpuncture by one person and immediately by another person will be assessed and recorded using the VAS Visual Pain Scale.

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Fax

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Email

pishgiri@yahoo.com

Web page address

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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mahboobeh Khajeh

Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

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