

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

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

2019-10-06, 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 Khatamolambia hospitals

**Full name of responsible person**

Bitra 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad Hassan Emamian

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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**

Bitra 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**

Ph.D.

**Other areas of specialty/work**

Nursery  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahroud University of Medical Sciences  
**Full name of responsible person**  
Bitra Koushki  
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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

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

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