

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of topical application of Rosemary essential oil on the severity of inflammation and pain induced by needle insertion into arterial venous fistula in patients undergoing chronic hemodialysis

#### Protocol summary

##### Study aim

The effect of topical application of rosemary essence on the severity of pain and inflammation caused by needle insertion into venous arterial fistula in hemodialysis patients

##### Design

The present study is a randomized controlled clinical trial on hemodialysis patients in hemodialysis ward of Golestan and Imam Khomeini Hospitals in Ahvaz, Iran. The present study will be propounded with the University Ethics Committee and then it will be started with permission from the Honorable Research Assistant. sample size according to the previous results of studies and the sample size formula is considered 60 people that will be divided into control and intervention groups by using block design.

##### Settings and conduct

The present study is a randomized controlled clinical trial on hemodialysis patients in hemodialysis ward of Golestan and Imam Khomeini Hospitals in Ahvaz, Iran. Sixty patients undergo hemodialysis in Golestan and Imam Khomeini Hospitals of Ahvaz in two groups of intervention and control. The severity of pain during pinching and inflammation of the fistula is measured in both control and intervention groups. 3 Puff of rosemary essential oil 5 minutes before surgery Hitting is used. After 5 minutes, the needle is disinfected and the needle is inserted. The placebo group uses 3 puff water spray

##### Participants/Inclusion and exclusion criteria

Age over 18 years, Perform three dialysis sessions per week, 6 months after fistula fixation

##### Intervention groups

At the time of the intervention, 3 puffs of rosemary essential oil will be applied 5 minutes before hemodialysis at the injection site. After 5 minutes, the injection site will be disinfected with alcohol and the needle will be inserted. In placebo group will be used 3

puff of water spray.

##### Main outcome variables

The severity of pain and inflammation caused by needle entry into the venous arterial fistula

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191028045263N1**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **retrospective**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

##### Registration date

2020-01-06, 1398/10/16

##### Registrant information

##### Name

roya maramazi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3391 8993

##### Email address

roya0939590@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-21, 1398/08/30

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of topical application of Rosemary essential oil on the severity of inflammation and pain induced by needle insertion into arterial venous fistula in patients undergoing chronic hemodialysis

**Public title**  
The Effect of Rosemary Essential Oil on Severity of Inflammation and Pain Due to Needle Entry to Intravenous Arterial Fistula in Hemodialysis Patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having Intravenous artery fistula Six month after fistula fixation Having three dialysis sessions in a week  
**Exclusion criteria:**  
Suffering Peripheral vascular disease Suffering Leukemia and acquired immune deficiency Patient dissatisfaction

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomized block design will be assigned to two intervention and control groups. Four blocks will be used in this study and the numbers will be assigned to them according to the following list (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then select random numbers from one to 6 (eg 1 4 5 and ...) and randomization will continue until the last participant.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Ahwaz University of Medical Sciences  
**Street address**  
No.51,fifteen Ave.,kianpars Blvd.,Ahwaz Town  
**City**  
Ahwaz  
**Province**  
Khouzestan  
**Postal code**  
6155873687

**Approval date**  
2019-10-25, 1398/08/03

**Ethics committee reference number**  
IR.AJUMS.REC.1398.545

## Health conditions studied

1

**Description of health condition studied**  
Severity of pain and inflammation induced by needle insertion into venous arterial fistula in patients undergoing chronic hemodialysis

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

**Description**  
severity of pain induced by needle insertion into arterial venous fistula

**Timepoint**  
Before intervention and during next six sessions of dialysis

**Method of measurement**  
Iran phlebitis checklist and Visual Analogue Scale

2

**Description**  
severity of inflammation induced by needle insertion into arterial venous fistula

**Timepoint**  
Before intervention and during next six sessions of dialysis

**Method of measurement**  
Iran phlebitis checklist and Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: The researcher will use 3 puffs of rosemary essential oil 5 minutes before hemodialysis at the time of intervention. After 5 minutes, the injection site will be disinfected with alcohol and the needle will be inserted. To control for confounding factors, the entire process of needle placement in the fistula will be performed by four nurses with at least six months of dialysis and researcher supervision. The type of needle will be the same in size, shape and manufacturer. Also, the needle will be placed in the fistula for all specimens with a 20-30 degree angle. The intervention will last for six sessions

### Category

Other

## 2

### Description

Control group: In the control group water spray is used, three puffs are sprayed at the needle insertion place for six intermittent sessions.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam khomeini hospital

##### Full name of responsible person

Leili Khashen

##### Street address

No.51,fifteen Ave.,kianpars Blvd.,Ahwaz Town

##### City

Ahwaz

##### Province

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##### Phone

+98 61 3391 8993

##### Email

roya0939590@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Golestan hospital

##### Full name of responsible person

Minoo Baratifar

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No.51,fifteen Ave.,kianpars Blvd.,Ahwaz Town

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Marziyeh Asadi Zaker

##### Street address

Golestan,Ahvaz University of Medical Sciences

##### City

Ahwaz

##### Province

Khouzestan

##### Postal code

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##### Phone

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##### Email

roya0939590@gmail.com

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Roya Maramazi

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

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Ahvaz University of Medical Sciences  
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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable