

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

Khouzestan

Postal code

6155873687

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

Street address

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

City

Ahwaz

Province

Khouzestan

Postal code

6155873687

Phone

+98 61 3391 8993

Email

roya0939590@gmail.com

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

6155873687

Phone

+98 61 3391 8993

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

Street address

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

City

Ahwaz
Province
Khouzestan
Postal code
6155873687
Phone
+98 61 3391 8993
Email
roya0939590@yahoo.com

Person responsible for scientific 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
Street address
Kianpars,15 st.
City
Ahvaz
Province
Khouzestan
Postal code
6155873687
Phone
+98 61 3391 8993
Fax
Email
roya0939590@gmail.com

Person responsible for updating data

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
Street address
Kianpars,15 st.
City
Ahvaz
Province
Khouzestan
Postal code
6155873687
Phone
+98 61 3391 8993
Fax
Email
roya0939590@gmail.com

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