Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of Satoria hortensis essential oil on pain caused by arteriovenous fistula puncture of patients undergoing hemodialysis: A randomized double-blinded placebo-controlled clinical trial

Protocol summary

Study aim

Reduction of pain caused by arteriovenous fistula needling in dialysis patients using a natural and herbal method. By examining the effect of this essential oil on reducing pain and improving the condition of patients, this research aims to improve the existing treatment methods and introduce new natural treatments with minimal complication methods to manage acute pain.

Design

Randomized double-blind crossover controlled clinical trial on 30 patients and Excel software will be used for randomization.

Settings and conduct

Patients were referred to the dialysis centers of Namazi and Shahid Faqihi hospitals of Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female patients with chronic kidney problems between 18 and 70 years old, dialysis at least 2 times a week, a history of dialysis through arteriovenous vessels for at least 3 months, and full consciousness and signing a written informed consent form. Exclusion criteria: Allergy to herbal products, skin disease and injury to the study site, use of oral analgesics in the past 6 hours or topical Arteriovenoussite pain medication in the past 24 hours, diabetic neuropathy or other types of neuropathy, failure of the initial attempt to achieve Arteriovenous vessels.

Intervention groups

For each patient, one tip of finger unit (TUF) of the gel (gel containing essential oil and placebo) will be applied within a radius of 2 cm from the entry point of the arteriovenous fistula (AVF). After ten minutes, an experienced nurse will puncture the AVF.

Main outcome variables

Demographic characteristics such as age, gender, educational status, and number of dialyses per week are recorded. The main outcome measure is the amount of pain during AVF needling, measured using the video analog scale (AVS). This scale is known as a valid and reliable tool.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121031011341N12**
Registration date: **2024-01-03, 1402/10/13**
Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**
Update count: **0**

Registration date

2024-01-03, 1402/10/13

Registrant information

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Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-15, 1402/10/25

Expected recruitment end date

2024-02-18, 1402/11/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of Satoria hortensis essential oil on pain caused by arteriovenous fistula puncture of patients undergoing hemodialysis: A randomized double-blinded placebo-controlled clinical trial

Public title
Investigating the effect of Satoria hortensis on hemodialysis needling pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic kidney disease Twice-weekly dialysis History of dialysis through arteriovenous fistula for a minimum of 3 months Full consciousness and sign a written consent for participation in the study
Exclusion criteria:
Allergy to herbal products Skin injuries to the site of arteriovenous fistula Consumption of oral sedatives in the past 6 hours or Local (arteriovenous fistula) pain medication in the past 24 hours Diabetic or other types of neuropathy Failure of the initial attempt to reach the arteriovenous fistula
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Placebo and Satoria hortensis gel
Randomization (investigator's opinion)
Randomized
Randomization description
To assign people to groups A and B, we will use the block of four method. The randomization list will be generated by a biostatistician using Excel software, and a third party will determine which groups are in treatment and which are placebo by throwing a coin.
Blinding (investigator's opinion)
Double blinded
Blinding description
Using similar non-transparent containers with consecutive numbering will guarantee the lack of information about the allocation to groups, which will be considered. Both types of gel (gel containing essential oil and placebo gel) will be the same in terms of physical characteristics (including consistency, color, and smell of the product). In addition, they will be packed in containers of the same shape and size. It should be noted that each container has a code that only the person who produced it knows about its contents, so patients, nurses, doctors, and researchers are unaware of the drugs used.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Science
Street address
Zand Avenue
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Approval date
2023-12-12, 1402/09/21
Ethics committee reference number
IR.SUMS.MED.REC.1402.400

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z49.0
ICD-10 code description
Preparatory care for renal dialysis

Primary outcomes

1

Description
Pain
Timepoint
immediately after needle insertion
Method of measurement
analog video scale (AVS)

Secondary outcomes

empty

Intervention groups

1

Description
Satoria hortensis essential oil will be applied on the insertion site of hemodialysis needles and remained for 10 minutes.
Category
Treatment - Drugs

2

Description
Control group: In placebo method, the gel of placebo would be applied on the insertion site of hemodialysis needles and remained for 10 minutes
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Aida Iraji
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2

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Shiraz 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
Shiraz University of Medical Sciences
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Mohammad Hashem Hashempur
Position
Assistant Professor of Shiraz University of Medical Sciences
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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

Not applicable