Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Aromatherapy with Salvia officinalis and topical lidocaine gel on pain intensity during insertion of vascular needles in patients undergoing hemodialysis

Protocol summary

Study aim

Comparison of the effect of aromatherapy with Salvia officinalis and topical lidocaine gel on pain intensity during insertion of vascular needles in patients undergoing hemodialysis

Design

This study is a clinical trial before and after. The sampling was done in the available method and 23 patients were randomly selected in 3 step: without intervention, intervention with topical lidocaine gel, and intervention with aromatherapy with Salvia officinalis from hemodialysis patients referred to the hemodialysis section.

Settings and conduct

From the hemodialysis patients referred to Allameh Bohlool Hospital in Gonabad, the patients who have entry criteria, 23 patients were selected and The written consent was taken and at the first step, for them a demographic questionnaire and visual analog scale without any intervention after insertion of vascular needles at the part of fistula or graft, completed and the second step, intervention with topical lidocaine gel was performed and the intensity of pain was measured immediately after needle insertion by visual analog scale. And in the third step, an intervention with aroma of Salvia officinalis on the samples is done and the pain intensity will be measured.

Participants/Inclusion and exclusion criteria

The population under study are hemodialysis patients who experience needle pain and should be: over 18 and alert, have a good smell and lack of sensitivity to herbal and non-addictive narcotics and Alcohol and non-compliance conditions including severe allergy during the study and dissatisfaction for the continuation of the study.

Intervention groups

intervention in three steps: without intervention and intervention with topical lidocaine gel and intervention with aroma of Salvia officinalis.

Main outcome variables

The intensity of the pain caused by the entry of vascular needles at the fistula or graft in patients undergoing hemodialysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190622043977N1**
Registration date: **2019-07-17, 1398/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-17, 1398/04/26**
Update count: **0**

Registration date

2019-07-17, 1398/04/26

Registrant information

Name

Bahareh Nikraftar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

bahar.nic.1358@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Aromatherapy with Salvia officinalis and topical lidocaine gel on pain intensity during insertion of vascular needles in patients undergoing hemodialysis

Public title

Comparison of the effect of Aromatherapy with Salvia officinalis and topical lidocaine gel on pain intensity during insertion of vascular needles in patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18 yr of age or older Lack of allergy to plants and the aroma No use of palliative about 6 hours ago No damaged skin at the desired part lake of known allergies or sensitivities to lidocaine, prilocaine or other local anesthetic Lack of olfactory disorder Lack of addiction to drugs and alcohol Having a minimum reading and writing literacy Being conscious patient Lack of severe pain in other places

Exclusion criteria:

Dissatisfaction to continue the research Death or hospitalization in other wards Allergy or critical reaction during the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Dr. Mahdizadeh Blvd.

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.GMU.REC.1398.043

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Measuring the severity of pain caused by needle insertion before any intervention and after intervention with topical lidocaine gel and intervention with the aromatherapy with Salvia officinalis

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 3: In the next meeting on the same group, intervention will be done with aromatherapy. An oil drop of a concentration of 10% Salvia officinalis aroma from Zardband Pharmaceuticals Company, 3 drops are dropped into gas of 4x4 cm and is attached 20cm away from the patient's nose to his collar and the patient breathes for 5 minutes normally, and after the

intervention, the severity of pain will be measured.

Category

Other

2

Description

Intervention group 2: The next session is an intervention with 2% lidocaine gel prepared in Sina-Darou Company, which is applied in the area of 5cm2 locally for 15 minutes before the needle is inserted. Then the gel is cleaned from the skin and the skin is disinfected to enter the vascular needle. The severity of the patient's pain will be evaluated and recorded immediately after needling by visual analog scale.

Category

Treatment - Drugs

3

Description

Intervention group 1: Patients first complete the demographic and visual analog scale based on inclusion criteria entry into the study and immediately be assessed and recorded without any intervention of pain caused by entery of needle in fistula or graft with visual analog scale.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlool Gonabadi Hospital

Full name of responsible person

Bahareh Nikraftar

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Vahdat Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Shahla Khosravan

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Bahareh Nikraftar

Position

Master of science

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity
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Mohammad Mojalli

Position
PhD in Nursing Education

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