

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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 5cm<sup>2</sup> 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 entry 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

**Street address**

Vahdat Blvd.

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691797852

**Phone**

+98 51 5723 6833

**Fax**

+98 51 5723 6160

**Email**

Bohloul@gmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr Shahla Khosravan

**Street address**

Dr. Mahdizadeh Blvd.

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Fax**

+98 51 5722 9025

**Email**

info@gmu.ac.ir

**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

**Street address**

Dr. Mahdizadeh Blvd.

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Fax**

+98 51 5722 9025

**Email**

bahar.nic.1358@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Mohammad Mojalli

**Position**

PhD in Nursing Education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Dr. Mahdizadeh Blvd.

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Fax**

+98 51 5722 9025

**Email**

Mojalli.m@gmu.ac.ir

## Person responsible for updating data

### 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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## 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