

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis.

#### Protocol summary

##### Study aim

Determining the effect of jasmine oil on sleep quality of patients undergoing hemodialysis in Sabzevar dialysis centers in 2021

##### Design

Randomized Clinical trial with control group, with parallel, single-blind, and outcome assessment

##### Settings and conduct

The location of the project performing will be Vasei Hospital and Kashefi Dialysis Center in Sabzevar. Hemodialysis patients who meet the inclusion criteria are divided into two groups using random allocation: intervention (receiving jasmine aroma) and control (not receiving jasmine aroma) for one month. before and after intervention sleep quality of patients measured and compared by Pittsburgh questionnaire. In this clinical trial, the statistician will be blinded with lack of information about data in two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: • Get a Pittsburgh questionnaire score greater than 5 • At least 18 years old and at most 70 years old • History of at least 6 months of hemodialysis • Perform hemodialysis at least twice a week for at least 3 hours each time • Having full consciousness exclusion criteria: • Significant hearing and speech disorders • Known respiratory problems such as asthma • Existence of olfactory disorder • Known mental illness and drug addiction

##### Intervention groups

The intervention group is exposed to 5 drops of jasmine oil every night before going to bed for a month with a cotton swab dipped in oil. This oil, which is prepared from the jasmine flower by Ben Marie method with a concentration of 50% by the Gold Company of Nature, contains the active ingredients of linalyl acetate and benzyl acetate. The control group will receive only standard therapeutic interventions during the study.

##### Main outcome variables

A sleep quality score based on the Pittsburgh Sleep

Quality Questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210217050396N1**

Registration date: **2021-03-27, 1400/01/07**

Registration timing: **prospective**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

##### Registration date

2021-03-27, 1400/01/07

##### Registrant information

##### Name

Alemeh Sultani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4465 6867

##### Email address

soltania98@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-09, 1400/01/20

##### Expected recruitment end date

2021-06-10, 1400/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis.

### Public title

The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Get a Pittsburgh questionnaire score greater than 5  
Having a minimum age of 18 and a maximum of 70 years  
Have a history of at least 6 months of hemodialysis  
Perform hemodialysis at least twice a week for at least 3 hours each time  
Having full consciousness

#### Exclusion criteria:

Significant hearing and speech disorders  
Known respiratory problems such as asthma  
Existence of olfactory disorder  
Known mental illness and drug addiction

### Age

From **18 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **58**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Samples will be selected by available sampling and will be randomly assigned to intervention and control groups using random allocation blocks. R Software will be used to get the blocks. The blocks are made up of 6 English letters (A,B,C,D,E,F). A ,B,C will be considered for the intervention group, and other three letters (D,E,F) will be considered for the control group. The blocks will be randomly selected in blindfolded manner. Each block will determine the order of entry in the intervention and control groups. Assuming choosing the DCAFBE block means from left hand, first, fourth and sixth, respectively, will be located in the control group, and the second, third, and fifth of participants will be located in the intervention group, respectively. Thus, ten blocks will be selected to complete the sampling.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, due to the lack of a placebo and researcher assistant, blinding the participant and the researcher will not be possible. Only the data analyzer is blinded due to lack of knowing the patients and giving data as A and B group to her.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar university of medical sciences

##### Street address

Vice Chancellor for Research and Technology ,  
University of Medical Sciences , Campus University ,  
above the Memorial of the Unknown Martyrs, Nuclear  
Martyrs Boulevard

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

#### Approval date

2021-03-15, 1399/12/25

#### Ethics committee reference number

IR.MEDSAB.REC.1399.196

## Health conditions studied

### 1

#### Description of health condition studied

Patients undergoing hemodialysis

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

Sleep quality score on the Pittsburgh questionnaire is less than 5

#### Timepoint

اندازه گیری کیفیت خواب در ابتدای مطالعه و یکماه پس از شروع استفاده از رایحه روغن یاسمین

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Every night for a month, before going to bed, they are exposed to 5 drops of jasmine oil. This oil, which is prepared from jasmine flowers by the Ben Marie method with a concentration of 50% by the Golden Nature Company, contains the active ingredients linalyl acetate and benzyl acetate. The method of using this oil in the present study is that we ask the patient or his companion to put 5 drops of Yasmin oil in a dropper containing 10 ccs of oil on a cotton ball each night before going to bed. Drop the prepared material and attach it to the collar of the research unit with a pin, and after waking up, remove it and throw it away. The method of use will be explained to the patient or his companion by the researcher in a practical way.

#### Category

Treatment - Other

### 2

#### Description

Control group: Since the aroma of any type of oil to be used as a placebo may affect the sleep quality of the control group units, we prefer not to use a placebo for these people. Therefore, the control group will receive only standard therapeutic interventions during the study. After one month, the sleep scores of the control and intervention groups are determined using the Pittsburgh questionnaire.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sabzevar Vasei Dialysis Center

##### Full name of responsible person

Alemeh Soltani

##### Street address

A large educational and medical hospital , Nuclear Martyrs Boulevard

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Sabzevar

##### Province

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##### Email

waseehospital@medsab.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mohammad Hossein Saghi

##### Street address

Vice Chancellor for Research and Technology , Nuclear Martyrs Boulevard above the Memorial of the Unknown Martyrs , Campus of the University of Medical Sciences ,

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##### Email

vc.Research@medsab.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

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Alemeh Soltani

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

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Mostafa Rad

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Associate Professor

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## Person responsible for updating data

**Contact**

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Alemeh Soltani

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Email**

SoltaniA98@medsab.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available