

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The effects of aromatherapy with Citrus aurantium on sleep quality of hemodialysis patients

#### Protocol summary

##### Summary

The presents study aimed to investigate The effect citrus aurantium on sleep quality hemodialysis patients. It is a clinical study and is not blinded. Inclusion Criteria: Having Consent form; Taking 5 points from Pittsburgh Sleep Quality Index ; Having experience of at least 6 month dialysis . exclusion Criteria:No tendency to continue the study; having reaction to citrus aurantium consumption. The Sample are 60 dialysis patients referring to Imam reza hospital. The intervention group(30 members) will take 3 drops of citrus aurantium with the concentration of10% every night by 3 deep breath for 4 weeks. Control group was monitored during the study and will do routine activities without any intervention. 4 weeks after the start of study the Pittsburgh Sleep Quality Index will be completed again

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2013052213423N1**

Registration date: **2015-08-31, 1394/06/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-31, 1394/06/09

##### Registrant information

###### Name

Seyed-Mousa mahdizadeh

###### Name of organization / entity

Faculty of nursing&midwifery mashhad university of medical scienceses

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3859 1511

###### Email address

mahdizadehm@mums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice Chancellor For Research Mashhad University of Medical Sciences

###### Expected recruitment start date

2014-12-22, 1393/10/01

###### Expected recruitment end date

2015-02-09, 1393/11/20

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effects of aromatherapy with Citrus aurantium on sleep quality of hemodialysis patients

###### Public title

The effect Citrus aurantium on sleep quality hemodialysis patients

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18 to 60; Having Consent form; Taking 5 points from Pittsburgh Sleep Quality Index (PSQI); Having experience of at least 6 months dialysis ; Having full awakesness and audio visual ability for learning of citrus aurantium consumption. exclusion Criteria:No tendency to continue the study; having reaction to citrus aurantium consumption; Having renal transplant; Moving to other place or hospital or dying of patient.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

University Ave Mshhad

##### City

Mashhad

##### Postal code

9137913199

#### Approval date

2014-10-23, 1393/08/01

#### Ethics committee reference number

930052

## Health conditions studied

### 1

#### Description of health condition studied

End stage renal failure

#### ICD-10 code

n18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

Sleep quality

#### Timepoint

Before the intervention, and one month after intervention

#### Method of measurement

Pittsburgh Sleep Quality Index

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

The intervention group: The intervention group(30 members) will take 3 drops of Citrus aurantium with the concentration of10% every night by 3 deep breath for 4 weeks

#### Category

Other

### 2

#### Description

Control group: Pittsburgh Sleep Quality Index will be completed at the beginning, and 4th week. No intervention for the control group

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza (AS)

##### Full name of responsible person

Hadi Rouhi

##### Street address

University Avenue, Avenue Ebn-e Sina, Imam Reza hospital

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor For Research Mashhad University of  
Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Building Qureshi , Mashhad

**City**

Mashhad

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice Chancellor For Research Mashhad University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Marzieh Imani

**Position**

Master science student of Intensive Care Nursing/

**Other areas of specialty/work****Street address**

University Avenue, School of Nursing and Midwifery

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Imanim911@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mousa Mahdizadeh

**Position**

MSc of Nursing, Lecturer, Faculty Member of Mashhad  
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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Marzieh Imani

**Position**

Special Nursing Graduate

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University Avenue, School of Nursing and Midwifery

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*