

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of Chamomile on Sleep Quality of Hemodialysis Patients

Protocol summary

Summary

Effect of Chamomile on sleep quality of hemodialysis patient will determined. Inclusion Criteria: Having Consent form; Taking 5 points from Pitzsburg test; Having at least 6 months dialysis experiences. Exclusion Criteria: No tendency to continue the study; having reaction to Chamomile consumption. The samples are 110 dialysis patients who come to Wali-e- Asr Hospital in Arak. The intervention group will take syrope of Chamomile 400 mg/Day at 21 to 22 Pm for 4 weeks. The control group will take syrope of Sakharin as the same. Quality of sleeping will measure at the beginning and after the intervention.

General information

Acronym

Effect of Chamomile on Sleep Quality

IRCT registration information

IRCT registration number: **IRCT2015051122218N1**
Registration date: **2015-06-12, 1394/03/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-12, 1394/03/22

Registrant information

Name

Vahid Moeini Ghamchini

Name of organization / entity

Neyshabour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 4062

Email address

v.moinighamchini@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Chamomile on Sleep Quality of Hemodialysis Patients

Public title

Effect of Chamomile on Sleep Quality of Hemodialysis Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18 to 65; Having Consent form; Taking 5 points from Pitzsburg test; Having at least 6 months dialysis experiences; Not having bad event during last 6 months; Having full awakesness and audio visual ability for learning Chamomile consumption
Exclusion Criteria: No tendency to continue the study; Suffering from each important diseases during the study; having reaction to Chamomile consumption; Having renal transplant; Pregnancy and feeding; No taking Chamomile for at least 3 days; Moving to other place or hospital and dying

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Sardasht

City

Arak

Postal code

Approval date

2015-04-20, 1394/01/31

Ethics committee reference number

IR.ARAKMU.REC.1394.12

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

Quality of sleep

Timepoint

Monthly

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Anxiety

Timepoint

Weekly

Method of measurement

Questionnaire

Intervention groups

1

Description

The control group will take syrope of Sakharin at 21 to 22 Pm for 4 weeks.

Category

Treatment - Drugs

2

Description

The intervention group will take syrope of Chamomile 400 mg/Day at 21 to 22 Pm for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie Asr Hospital

Full name of responsible person

Vahid Moeini Ghamchini

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rafiei

Street address

Sardasht

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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