

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of Effect of Noma Syrup (Lactuca sativa leaf extract) with Clonazepam Tablet on Insomnia Severity in Hemodialysis Patients

Protocol summary

Study aim

Determining the effect of Noma syrup (Lactuca sativa leaf extract) with clonazepam tablets on the severity of insomnia in hemodialysis patients.

Design

Clinical trial with control group, 102 patients were randomly assigned to two groups of 51 patients receiving Noma syrup and control (receiving clonazepam tablets) according to the computer program Permuted Block Randomization.

Settings and conduct

intervention group drink Noma syrup containing 240 ml every night for 20 ml, half an hour before bedtime for two weeks. The drug in the control group is clonazepam tablets, which will be given 0.5 mg of clonazepam tablets every night, half an hour before bedtime, for two weeks to the subjects in the control group. The severity of insomnia with the ISI index is completed before the start of the study and after two weeks of medication. The place of study is the Shahrvand center of Sari city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People 18 years and older with insomnia problem, hemodialysis two or three times a week, Iranian nationality, mental alertness, ability to answer questions, no delirium, no cognitive problems, no history of stroke and Incurable diseases such as cancer, no severe hearing and vision problems and substance abuse. Exclusion criteria: Patients taking anti-anxiety or hypnotic drugs. Patients using accompanying therapies such as acupuncture, herbal remedies, hypnosis or yoga. The patient's unwillingness to continue the study, exacerbation of sleep disorders, delirium, allergic reaction or death of the patient are the exclusion criteria.

Intervention groups

In the intervention group, Noma syrup is consumed 20 ml every night, 30 minute before going to bed for two weeks. In the control group, clonazepam tablets will be given 0.5 mg of clonazepam tablets every night, 30 minute before bedtime, for two weeks.

Main outcome variables

Insomnia Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N37**

Registration date: **2021-06-22, 1400/04/01**

Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **0**

Registration date

2021-06-22, 1400/04/01

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Effect of Noma Syrup (Lactuca sativa leaf extract) with Clonazepam Tablet on Insomnia Severity in Hemodialysis Patients

Public title
The Effect of Noma syrup on insomnia in hemodialysis patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People 18 years and older with insomnia hemodialysis two or three times a week Iranian nationality mental alertness and ability to answer questions lack of delirium (Delirium Screening Nursing Scale (NE-DESC)) Lack Existence of cognitive problems (examination by MMSE test) no history of stroke Lack of incurable diseases such as cancer Absence of severe hearing and vision problems No substance abuse
Exclusion criteria:
Patients taking anti-anxiety or hypnotic drugs due to neuropsychiatric disorders Patients using combination therapies such as acupuncture, herbal remedies, hypnosis or yoga The patient's unwillingness to continue participating in the study Exacerbation of sleep disorder Delirium incidence Allergic reaction or death of the patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals are randomly assigned to two groups of 51 intervention and control using random numbers provided by computer software and Permuted Block Randomization by a statistical consultant. 25 blocks of 4 and one block of 2 so that in blocks of 4, two people from the intervention group and two people from the control group and in the block of two, one person from the intervention group and one person from the control group . Therefore, 102 envelopes are designed and the letter A (intervention group) and the letter B (control group) are embedded in it based on the information obtained from the computer program. Envelopes are numbered from one to 102. Respectively, the first patient who is admitted to the ward and has the inclusion criteria enters the study after obtaining informed written consent and sampling continues until patient number 102.

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 Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City
Sari

Province
Mazandaran

Postal code
4816715793

Approval date
2021-06-13, 1400/03/23

Ethics committee reference number
IR.MAZUMS.REC.1400.245

Health conditions studied

1

Description of health condition studied
Insomnia severity

ICD-10 code
G47.00

ICD-10 code description
Insomnia, unspecified

Primary outcomes

1

Description
Insomnia Severity

Timepoint
Before the intervention and after the intervention

Method of measurement
Insomnia Intensity Scale

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: Noma syrup containing 240 ml of processed lettuce leaf extract is consumed 20 ml every night, half an hour before going to bed for two weeks.

Category

Treatment - Drugs

2

Description

Control group: Clonazepam tablets will be given half a mg each night, half an hour before bedtime, for two weeks to subjects in the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of Shahrvand Kidney Patients Center

Full name of responsible person

Arash Azad Farzin

Street address

Mazandaran University of Medical Sciences ,valiye asr highway, Joybar 3way ,Imam Sq,Sari, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Masoumeh Bagheri Nesami

Position

PhD in Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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 informatio

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