Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigation of the efficacy of lettuce seed extract syrup in the treatment of insomnia of cancer patients, a double blind randomized placebo controlled clinical trial

Protocol summary

Study aim
To determine the efficacy and safety of lettuce seed in the treatment of insomnia of cancer patients

Design
Two arm parallel group randomized clinical trial, double blinded

Settings and conduct
Patients with cancer referring to Shohaday-e- Tajrish Hospital of Tehran suffering from insomnia. In order to blind the investigator, medications are named as "A" for syrup of lettuce seeds extract and B for placebo. The patients don't aware of the type of drug she/ he is assigned to. In addition, the groups are entered into statistical analysis as "A" and "B

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Men and women with any type of cancer suffering from insomnia for at least 3 months 2. Patients with Pittsburgh sleep quality index score more than 5*** Exclusion criteria: 1. Diabetic patients 2. Lack of consent to participate in the study 3. Patients with systemic disease (except the cancer) 4.Patients who are taking hypnotic drugs

Intervention groups
Intervention group:Patients of intervention group will receive 5 cc syrup containing 1000 mg of the lettuce seeds extract every night for 2 weeks.*** Control group: Patients of placebo group will receive 5 cc syrup containing 1000 mg starch powder every night for 2 weeks.

Main outcome variables
Quality sleep index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N13**
Registration date: **2019-08-30, 1398/06/08**
Registration timing: **retrospective**

Last update: **2019-08-30, 1398/06/08**
Update count: **0**

Registration date
2019-08-30, 1398/06/08

Registrant information

Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3212 5592

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parvizim@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-23, 1397/04/02

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
2018-08-23, 1397/06/01

Actual recruitment end date
2019-06-20, 1398/03/30

Trial completion date
2019-06-20, 1398/03/30

Scientific title
Investigation of the efficacy of lettuce seed extract syrup in the treatment of insomnia of cancer patients, a double blind randomized placebo controlled clinical trial

Public title
Investigation of the efficacy of lettuce seed extract syrup in the treatment of insomnia of cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with any type of cancer suffering from insomnia for at least 3 months Patients with Pittsburgh sleep quality index score more than 5
Exclusion criteria:
Diabetic patients Lack of consent to participate in the study Patients with systemic disease (except the cancer) Patients who are taking hypnotic drugs.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization schedule is done by using Random Allocation software and create block randomization table.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape and packing of lettuce seed syrup and placebo are similar. Also in this study, the researcher, patient, and statistical analyst will identify the lettuce seed syrup as A and the placebo as B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2018-07-29, 1397/05/07
Ethics committee reference number
IR.SUMS.REC.1397.417

Health conditions studied

1

Description of health condition studied
insomnia
ICD-10 code
G47.01
ICD-10 code description
Insomnia due to medical condition

Primary outcomes

1

Description
Sleep quality
Timepoint
At the beginning of the study and two weeks after beginning of the study
Method of measurement
Pittsburgh sleep quality index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients of intervention group will receive 5 cc syrup containing 1000 mg of the lettuce seeds extract every night for 2 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients of placebo group will receive 5 cc syrup containing 1000 mg starch powder every night for 2 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohay-e-Tahrish Hospital

Full name of responsible person
Dr. Ghazaleh Heydarirad

Street address
Tajrish Square, Shohaday-e-Tejarish Hospital

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Younes Ghasemi

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Seyed Hamdollah Mosavat

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data and the result of the clinical trial
When the data will become available and for how long
6 month later
To whom data/document is available
Researchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
En Sending Email to the researchers
What processes are involved for a request to access data/document
Sending the request via the email
Comments