

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)

Phone

+98 71 3212 5592

Email address

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

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 9201

Email

ghazalrad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

Street address

7th floor, Vice Chancellor of Research, Shiraz
University of Medical Sciences, Zand Blvd., Shiraz,
Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

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

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3230 5646

Email

hamdi_88114@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shiraz University of Medical Sciences

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3230 5646

Email

hamdi_88114@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Parvizi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 1087

Email

mmparvizi@gmail.com

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