

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Effect of lettuce seed oil extract on treatment of insomnia in pregnant women and study of urinary melatonin before and after taking

#### Protocol summary

##### Study aim

The effect of lettuce seed oil on insomnia during pregnancy and evaluation of melatonin level before and after intervention

##### Design

clinical trial with control group; With Parallel groups; Double blinded; randomized; design of 90 patients

##### Settings and conduct

Both groups will also request to fill in a questionnaire. Before start of treatment the patients will be ask to collect a first morning urine sample . At the end of treatment again patients will ask to collect a first morning urine sample and also refuel sleep questionnaire and efficacy drug will be evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with aged between 20-45 years. Gestational aged between 26 and 32weeks Women with Pittsburgh sleep quality index score more than 5. Exclusion criteria: Patients who don't have suffer from insomnia before pregnancy. high risk pregnancy (multiple pregnancy, threatened abortion, preeclampsia, ...) Patients who don't have contraindication of doing exercise during pregnancy.

##### Intervention groups

Intervention group: 45 patients will be treated by lettuce seed oil twice daily from beginning of study within 2 weeks. control group: will be received placebo manufactured by Shiraz pharmacy school with the same method.

##### Main outcome variables

Finally, urinary melatonin levels are compared before and after treatment and the effectiveness of this treatment is evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140525017827N7**

Registration date: **2019-10-22, 1398/07/30**

Registration timing: **prospective**

Last update: **2019-10-22, 1398/07/30**

Update count: **0**

##### Registration date

2019-10-22, 1398/07/30

##### Registrant information

###### Name

Nasrin Asadi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1233 2365

###### Email address

asadin@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of lettuce seed oil extract on treatment of insomnia in pregnant women and study of urinary melatonin before and after taking

**Public title**

The effect of lettuce seed oil on insomnia in pregnancy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with aged between 20-45 years Gestational aged between 23-26 weeks with Pittsburgh sleep quality index score more than 5

**Exclusion criteria:**

Patient must not have been taking hypnotic drug Interventions and outcomeshigh risk pregnancy (Multiple pregnancy, gestational diabetes mellitus, hypertension, preeclampsia, ..... ) patients must not have suffered from insomnia before pregnancy patients must not have been treated by LS oil within the preceding year patient must not have been taking hypnotic drug

**Age**

From **20 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software Minitab; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use similar bottles

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

lettuce seed oil and placebo have been administered in the similar bottles, so patients and researchers were unable to detect which one was Pentoxifylline or placebo. Our nurse colleague in this study in Hafez hospital delivered formulations to the participants of the study according to the randomized block table. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

**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**

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

34786-71946

**Approval date**

2019-05-20, 1398/02/30

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.164

**Health conditions studied****1****Description of health condition studied**

Nonorganic insomnia

**ICD-10 code**

F51.0

**ICD-10 code description**

maternal disorders predominantly related to pregnancy

**Primary outcomes****1****Description**

Measurment of urine Melatoninine

**Timepoint**

Before and after treatment

**Method of measurement**

ELISA

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: lettuce seed oil twice daily for 14 days

**Category**

Treatment - Drugs

## 2

### Description

Control group: Placebo twice a day for 14 days made by the Faculty of Pharmacy of Shiraz university of medical sciences.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hafez Clinic of Shiraz University of Medical Sciences

##### Full name of responsible person

Amolbanin Hassani

##### Street address

Hafez Clinic, Chamran blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

34786-71946

##### Phone

+98 71 3612 8257

##### Email

banin.hassani5349@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Yoones Ghasemi

##### Street address

Building of Shiraz University of Medical Sciences,  
Zand Ave

##### City

Shiraz

##### Province

Fars

##### Postal code

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##### Phone

+98 71 3235 7282

##### Email

ghasemiy@sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### 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

Omolbanin Hassani

##### Position

Resident of obstetrics and gynecology

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Department of obstetrics and gynecology, Shahid  
Faghihi Hospital, Zand St, Shiraz, Iran

##### City

Shiraz

##### Province

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##### Postal code

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##### Phone

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##### Email

banin.hassani5349@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Nasrin Asadi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Maternal- Fetal Medicine (Perinatology) research  
center, Hafez Hospital, Chamran Ave., Shiraz

##### City

Shiraz

##### Province

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##### Postal code

34786-71946

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**Email**

nasadi2012@yahoo.ca

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nasrin Asadi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Maternal- Fetal Medicine (Perinatology) research center, Hafez Hospital, Chamran Ave., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

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**Phone**

+98 71 3612 8257

**Email**

nasadi2012@yahoo.ca

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

**When the data will become available and for how long**

IPD: 2019 Ethic form: 2019

**To whom data/document is available**

IPD: Researcher & Patient Ethic form: Patient

**Under which criteria data/document could be used**

IPD: Ethic form: Awareness of test results

**From where data/document is obtainable**

IPD: OB & Gyn ward Shiraz university of medical sciences  
Ethic form: OB & Gyn ward Shiraz university of medical sciences

**What processes are involved for a request to access data/document**

IPD: Vice chancellor Ethic form: Vice chancellor

**Comments**