

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of the effect of Horse Chestnut seed extract spray on improving and reducing the symptoms of sleep apnea

#### Protocol summary

Registration timing: **prospective**

##### Study aim

Determining the effect of Horse Chestnut seed extract spray on improving and reducing the symptoms of sleep apnea

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

##### Registration date

2022-09-05, 1401/06/14

##### Design

Phase 2 clinical trial on 40 patients with sleep apnea in Razi Hospital

##### Registrant information

###### Name

Seyyed Mohammad Mousavi Mirzaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3162 6020

###### Email address

mousavim903@bums.ac.ir

##### Settings and conduct

This clinical trial will be performed on 40 patients over 18 years with sleep apnea in Razi Hospital at Birjand. Patients will receive inhalation of Horse Chestnut seed extract intranasally as one puff in each nostril every 8 hours for 14 days.

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Sleep disorder, Nocturnal snoring, Daily fatigue, Uncontrolled blood pressure, Pittsburgh Sleep Quality Index $\geq 6$ ; Exclusion criteria: Patients with a history of liver and kidney disease, Pregnant and lactating women, Children under 18 years old, Anticoagulant consumption and continuous use of aspirin, Having a cardiac pacemaker, History of allergy to any chemical, herbal, or medicinal compound, Patients with a history of taking various narcotic and psychoactive drugs

##### Expected recruitment start date

2022-09-11, 1401/06/20

##### Expected recruitment end date

2022-11-11, 1401/08/20

##### Intervention groups

Intervention group: Inhalation of one puff of Horse Chestnut seed extract spray every 8 hours inside each nostril for 14 days (Preparation of extract in Faculty of Pharmacy of Birjand)

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Main outcome variables

Pittsburgh Sleep Quality Index, Adverse effects

##### Trial completion date

empty

#### General information

##### Scientific title

Evaluation of the effect of Horse Chestnut seed extract spray on improving and reducing the symptoms of sleep apnea

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201228049868N3**

Registration date: **2022-09-05, 1401/06/14**

##### Public title

Evaluation of the effect of Horse Chestnut seed extract spray on sleep apnea

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Sleep disorder Nocturnal snoring Daily fatigue  
Uncontrolled blood pressure Pittsburgh Sleep Quality  
Index $\geq 6$

### Exclusion criteria:

Patients with a history of liver and kidney disease  
Pregnant and lactating women Children under 18 years  
old Anticoagulant consumption and continuous use of  
aspirin Having a cardiac pacemaker History of allergy to  
any chemical, herbal, or medicinal compound Patients  
with a history of taking various narcotic and  
psychoactive drugs

## Age

From **18 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Ministry of Defence and  
Armed Forces Logistics

##### Street address

Shahid Langari St., Nobonyad Square., Pasdaran St

##### City

Tehran

##### Province

Tehran

##### Postal code

1693715817

#### Approval date

2021-11-11, 1400/08/20

#### Ethics committee reference number

IR.CHAMRANHOSPITAL.REC.1400.007

## Health conditions studied

### 1

#### Description of health condition studied

Sleep apnea

#### ICD-10 code

G47.3

#### ICD-10 code description

Sleep apnea

## Primary outcomes

### 1

#### Description

Pittsburgh Sleep Quality Index

#### Timepoint

Before the intervention and 14 days after the  
intervention

#### Method of measurement

Pittsburgh Sleep Quality Index

## Secondary outcomes

### 1

#### Description

Adverse effects

#### Timepoint

14 days after the intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Inhalation of one puff of Horse  
Chestnut seed extract spray every 8 hours inside each  
nostril for 14 days (Preparation of extract in Faculty of  
Pharmacy of Birjand)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Seyyed Mohammad Mousavi Mirzaei

##### Street address

Razi Hospital, Ghaffari Street

##### City

Birjand

##### Province

South Khorasan

**Postal code**  
9717844471  
**Phone**  
+98 56 3162 6000  
**Email**  
mousavim903@bums.ac.ir

**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717844471  
**Phone**  
+98 56 3162 6000  
**Email**  
mousavim903@bums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Miri  
**Street address**  
Birjand University of Medical Sciences, Ghaffari Street  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3238 1200  
**Email**  
research@bums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Birjand 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**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Seyyed Mohammad Mousavi Mirzaei  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Neurology  
**Street address**  
Razi Hospital, Ghaffari Street

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Seyyed Mohammad Mousavi Mirzaei  
**Position**  
Assistant professor  
**Latest degree**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
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**Email**

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

make this available

### **Informed Consent Form**

Undecided - It is not yet known if there will be 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