

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

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

Protocol summary

Study aim

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

Design

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

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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Sleep disorder, Nocturnal snoring, Daily fatigue, Uncontrolled blood pressure, Pittsburgh Sleep Quality Index ≥ 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

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)

Main outcome variables

Pittsburgh Sleep Quality Index, Adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201228049868N3**

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

Registration timing: **prospective**

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

Update count: **0**

Registration date

2022-09-05, 1401/06/14

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

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

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
Specialist
Other areas of specialty/work
Neurology
Street address
Razi Hospital, Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code
9717844471
Phone
+98 56 3162 6000
Email
mousavim903@bums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Seyyed Mohammad Mousavi Mirzaei
Position
Assistant professor
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+98 56 3162 6000
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