Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Lippia Citriodora effect on Sleep DisorderversusOilineffective: A double blind study

Protocol summary

Summary

Main goal:Assessment of Lippia Citriodoras Oil effect on Sleep Disorder versus ineffective Oil Design and Method: The statistical population of this study is all people over 60 years old with sleep disorder in elders of care centers of Tehran. This study is a randomized, double-blind clinical trial. Before randomization, the eligibility criteria will be checked by gathering the information about the disease and drugs of elders, recorded and examined according to their medical records and then questions asked from elders who have used drugs affecting on sleep disorders about having sleep-related problems. Then the study and details of intervention will be explained by the interviewer, and the patients will enter to the study after signing the informed consent. Patients will be assigned to the intervention and control groups based on Balanced Block Randomization. In the control group two drops ineffective oil and in the intervention group two drops Lemon verbena Oil will be administered in the nose morning and night. Basic information, including Pittsburgh Sleep Quality, and Demographic questionnaire will be asked in the beginning, 2 and 4 weeks after starting the medications. Patients will be asked for probable complications. Main outcomes: improving subjective quality of sleep and increasing sleep efficiency. Since the Lemon verbena medicine has scent and Placebo is scentless, for blinding intervention and control patients, the drugs are put near each other in order to take Lemon verbena smell and also a little amount of Lemon verbena oil will be sprayed on the medicine container.

General information

Acronym

insomnia

IRCT registration information

IRCT registration number: **IRCT2016061528485N1**
Registration date: **2016-12-23, 1395/10/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

seyran mohamadi bolban abad

Name of organization / entity

University of Rehabilitation Sciences and Social Welfare

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Aging Research Center, University of Social Welfare and Rehabilitation

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Lippia Citriodora effect on Sleep DisorderversusOilineffective: A double blind study

Public title
Assessment of Lippia Citriodora effect on Sleep DisorderversusOilineffective: A double blind study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria (inclusion): Tendency to participate in the study؛ Having over 60 years old؛ Having sleep disorders, in self-reported, or clinical level, and according to the Pittsburgh questionnaire؛ Ability of respond to the questionnaire؛ No history of any allergy, to lemon verbena, or mangroves plants؛ No continuous using from (twice or more in per week) from lemon Herbal Tea, or lemon extract over 1 month ago؛ No problems with the airway and nasal obstruction Exclusion criteria (exclusion): Having dependence or addiction to alcohol , drugs and medicines؛ Having disease, like that heart failure, respiratory disorders, and diseases of sleep, and wake-up cycle such as, respiratory apnea, and restless leg syndrome؛ Using from Effective drugs, on the sleep and wake up cycle (except previous prescribed drugs)
Age
From **60 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Rehabilitation Sciences and Social Welfare
Street address
koodakyar deadlock Boulevard student Evin field Tehran
City
Tehran
Postal code
1985713834

Approval date
2016-05-23, 1395/03/03
Ethics committee reference number
IR.USWR.REC.1395.50

Health conditions studied

1

Description of health condition studied
sleep disorder
ICD-10 code
G47.0
ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
Improve sleep quality
Timepoint
Intervention. Two weeks after starting treatment and after the treatment (4 weeks after the intervention)
Method of measurement
questionnaire

Secondary outcomes

1

Description
Improve sleep Subjective quality
Timepoint
Early intervention. 2 weeks after starting intervention and 4week after intervention
Method of measurement
questionnaire

Intervention groups

1

Description
In the control group using vegetable oils in lemon and control groups using inert oil (liquid paraffin)
Category
Placebo

2

Description
dropping two drops of inert oil in the nose morning and night
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kahrizak Charity Foundation in tehran

Full name of responsible person

Street address

Kahrizak, the end of the boulevard Doctor Hakim zadeh. Qom old road after Bhsht zahra, Tehran,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Welfare and Rehabilitation Research Center

Full name of responsible person

Robab Sahaf

Street address

Kodakyar deadlock Boulevard student Evin field . Welfare and Rehabilitation Sciences University / Center for Aging Research. Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Welfare and Rehabilitation Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty