Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical assessment of herbal inhalation of Hydroalcoholic Extract of lavender, Coriandrum sativum, Zataria multiflora, Mentha piperita, in treatment of Sinus Headache: A Randomized Double Blind Clinical Trial

Protocol summary

Study aim
Determination of the Effect of Herbal Formulation on Sinus Headache in Patients

Design
In this study, 64 patients were classified into control and Intervention groups by stratified randomization method Based on age.

Settings and conduct
This double-blind clinical trial study is performed in Imam Ali sub-specialty clinic.

Participants/Inclusion and exclusion criteria
People with a history of sinusitis assessed by the physician, with no history of migraine headaches, having at least three other symptoms of sinusitis such as nasal congestion and people with pain in one or more than one sinuses.

Intervention groups
In the intervention group, every 8 hours, patients add 5 ml of the drug to 250 ml of boiling water and inhale the vapor of it for 15 minutes. The control group will be given the placebo exactly the same as an inhaled drug (without active ingredient); and Duration of the using drug is two weeks in both groups.

Main outcome variables
Headaches associated with sinusitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170705034918N2**
Registration date: **2018-09-09, 1397/06/18**
Registration timing: **retrospective**

Last update: **2018-09-09, 1397/06/18**
Update count: **0**

Registration date
2018-09-09, 1397/06/18

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3333 6539
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st-heidari.r@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-07-06, 1397/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical assessment of herbal inhalation of Hydroalcoholic Extract of lavender, Coriandrum sativum, Zataria multiflora, Mentha piperita, in treatment of Sinus Headache: A Randomized Double Blind Clinical Trial

Public title
The effect of herbal inhalation of Hydroalcoholic Extract of lavender, Coriandrum sativum, Zataria multiflora, Mentha piperita, in treatment of Sinus Headache

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with a history of sinusitis assessed by the physician. People with no history of migraine headaches. People having at least three other symptoms of sinusitis such as nasal congestion. People with pain in one or more than one sinuses.

Exclusion criteria:

People who have ulcer in their mouth and nose. People Having a history of allergy

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomized collection will be done Based on age and gender; In such a way male and female patients will be assigned to the control and intervention group individually; and Randomization will be done by Random Allocation Software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Pharmaceutical and placebo products, with the same packaging, are categorized as A and B; And All phases of pharmaceutical formula and placebo preparation are carried out by a pharmacognosit co-worker. it should be noted that researcher and also patients will not be informed of the contents of any products.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahrekord University of Medical Sciences

Street address

Kashani Blvd, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.skums.rec.1396.87

Health conditions studied

1

Description of health condition studied

Sinus Headache

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Headaches

Timepoint

Before and two weeks after the intervention

Method of measurement

Based on VAS criteria

2

Description

Rhinorrhea

Timepoint

Before and two weeks after the intervention

Method of measurement

Self-reported

3

Description

Nasal congestion

Timepoint

Before and two weeks after the intervention

Method of measurement

Self-reported

4

Description

Dyspnea

Timepoint

Before and two weeks after the intervention

Method of measurement

Self-reported

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, every 8 hours, patients add 5 ml of the drug to 250 ml of boiling water and inhale the vapor of it for 15 minutes and the patients and researchers will not be aware of the contents of the drug and the placebo. The drug used in the intervention group contains a hydroalcoholic extracts of lavender, Coriandrum sativum, Zataria multiflora and Mentha piperita in a specified proportion according to the method mentioned in the British Pharmacopoeia, and the formulation will be prepared by the pharmacognostic colleagues. (Duration of the using drug is 14 days)

Category
Treatment - Drugs

2

Description
In the control group, patients will be given placebo every 8 hours, they add 5 ml of the placebo to 250 ml of boiling water and inhale the vapor of it for 15 minutes and Duration of the using placebo is 14 days. The placebo contains a Food coloring with no active ingredient and the same as the original medicine will be designed and packaged so the patients and researchers will not be aware of the contents of the the placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali sub-specialty clinic

Full name of responsible person
Maryam Kazemi

Street address
Shariati Ave.

City
Shahrekord

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Chahar-Mahal-va-Bakhtiari

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heidari.reza1995@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Reza Heidari-souresgjani

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Kashani Blvd.

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Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Reza Heidari-soureshjani

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Associate professor

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Medical Pharmacy

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Personal information of patients is confidential.

When the data will become available and for how long
The beginning of the data access period is after collecting and analyzing them until the paper is published.

To whom data/document is available
Executor of plan

Under which criteria data/document could be used
In order to analyze and review the results of the study

From where data/document is obtainable
Executor of plan

What processes are involved for a request to access data/document
The Information is not given to people who are not responsible for the research.

Comments