Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Elucidation of sinusitis based on Traditional Persian Medicine (TPM) and comparison of the TPM therapeutic protocol efficacy on chronic sinusitis with classic treatment: Mixed Methods

Protocol summary

Summary
Objective: to determine the effectiveness of the treatment protocol based on traditional medicine on chronic sinusitis, compared to classical drug therapy. Study design: non-randomized, not-blinded, non placebo-controlled, multi-center, phase I trial study. Trial method includes: Main inclusion criteria (nasal obstruction or congestion, anterior or posterior nasal discharge, facial pain or pressure, and reduction or loss of smell). Main exclusion criteria (acute bacterial infection of the respiratory tract, anatomical obstructions requiring surgery, allergies or other contraindications to the drug combination in patients, pregnancy, immune deficiency or Hypertension). Sample size: 52 patient. Intervention or interventions studied: Endoscopy and CT scan diagnosis - treatment with therapeutic package. Intervention time: 8 to 12 weeks. Primary outcome or consequences of the study: a reduction or improvement in the symptoms of patients on the standard scale evaluation (SNOT22)

General information

Acronym
TPM: Traditional Persian Medicine, EP3OS: European Position Paper on Rhinosinusitis and Nasal Polyp

IRCT registration information
IRCT registration number: **IRCT2015112425217N1**
Registration date: **2016-01-31, 1394/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2016-01-31, 1394/11/11

Registrant information
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Mashhad University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research,Mashhad University of Medical Sciences

Expected recruitment start date
2015-12-22, 1394/10/01
Expected recruitment end date
2016-02-20, 1394/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Elucidation of sinusitis based on Traditional Persian Medicine (TPM) and comparison of the TPM therapeutic protocol efficacy on chronic sinusitis with classic treatment: Mixed Methods

Public title
Effect of a herbal medicine combinations in the treatment of chronic sinusitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Two criteria of the main criteria

(including: nasal obstruction or congestion; anterior or posterior nasal secretion; facial pain or pressure; and reduction or loss of smell) or one major criterion and two minor criteria (including dental pain; cough; pain; pressure or fullness feel in ears; fatigue; headache or halitosis) for more than 12 weeks during the past 12 months. Exclusion criteria: Chronic sinusitis along with acute bacterial infections of the respiratory tract; Chronic sinusitis along with anatomical obstructions requiring surgery; Sensitivity or contraindication to the drug components; Pregnancy; Immunodeficiency; The presence of high blood pressure (hypertension history or blood pressure on admission greater than 140/90 mm Hg)

Age

From **18 years** old to **49 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences, Central office of Mashhad University of Medical Sciences, Daneshgah Ave., Mashhad, Iran

City

Mashhad

Postal code

91388-13944

Approval date

2015-12-07, 1394/09/16

Ethics committee reference number

IR.MUMS.REC.1394.504

Health conditions studied

1

Description of health condition studied

Chronic sinusitis

ICD-10 code

J32

ICD-10 code description

J32Chronic sinusitis Incl.: abscess, empyema, infection, suppuration (chronic) of sinus (accessory)(nasal

Primary outcomes

1

Description

Symptoms of chronic sinusitis

Timepoint

Baseline and sixth, eighth and twelfth week after intervention

Method of measurement

SNOT22 Questionnaire

Secondary outcomes

1

Description

Paranasal sinuses status

Timepoint

Before the intervention and twelve weeks after beginning intervention

Method of measurement

Lund-Mackey Score

2

Description

Symptoms of cold Coryza (Zokam) and Catarrh (Nazlah)

Timepoint

Before the intervention and twelve weeks after intervention beginning

Method of measurement

cold Coryza (Zokam) and Catarrh (Nazlah) questionnaire

Intervention groups

1

Description

Intervention group: Oral drug: Marjoram and licorice herbal tea, dose: 5 grams of pack contains 3 grams of leaves of marjoram and 2 grams of licorice root, every 8 hours, the duration of treatment (consumption): 8 weeks; If there is no improvement in symptoms for up to 12 weeks will continue. How to use: patient should be infuse the contents of each packet with 200 ml of boiling water in the pot for 20 minutes and after clearing, to be drink slowly at a temperature close lukewarm to hot , divided by maintaining an hour away from food, . Local drug:

Lavender oil on base of olive oil, dosage: 3-2 drops once a day (at night), the duration of treatment (consumption): 8 weeks; if there is no improvement in symptoms for up to 12 weeks will continue. Education: patients of this group on the basis of written instructions that will be placed at their disposal, will be avoided from harmful foods for cold and catarrh (such as yogurt, buttermilk, cheese, dough bread , bananas, vinegar, ...).

Category

Treatment - Drugs

2

Description

Control group: Prescription drugs include: Inhaled corticosteroid (Fluxinase), at a rate of 2 inhalations per day; along with daily nose irrigation with normal saline in the morning and evening. If there is no improvement, a systemic steroids will be administrated (prednisone tablets 1 mg / kg; that will be tapered within a short time). If there is evidence of purulent sinusitis, antibiotic treatment with azithromycin capsules of 250 mg daily for 4 weeks will be added to the treatment protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic for ear, nose and throat diseases, Imam Reza (AS) Hospital

Full name of responsible person

Dr. Mehdi Bakhshaee , Ear, nose and throat specialist, Associate professor

Street address

Special clinic for ear, nose and throat diseases, Imam Reza Sq, Ibn Sina St., Mashhad.

City

Mashhad

2

Recruitment center

Name of recruitment center

Special clinic for Persian Traditional Medicine, Imam Reza (AS) Hospital

Full name of responsible person

Dr. Majid Anushiravani, Persian Traditional Medicine Specialist, Assistant Professor

Street address

Special clinic for Persian Traditional Medicine, Imam Reza Sq, Ibn Sina St., Mashhad.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi, Research Vice Chancellor

Street address

Vice Chancellery for Research of Mashhad University of Medical Sciences, Mashhad University of Medical Sciences, Golestan Crossroads, Daneshgah Ave, Mashhad, Iran

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Mashhad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellery for Research of Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences, Faculty of Traditional and Complementary Medicine

Full name of responsible person

Dr. Mohammad Reza Mehri

Position

Persian Traditional Medicine Student

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