

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the Effect of Matricaria Chamomilla on Quality of Life in Patients with Chronic Rhinosinusitis Referred to Amirmounin Hospital in Rasht

Protocol summary

Study aim

Determination of the effect of matricaria chamomilla on quality of life in patients with chronic rhinosinusitis referred to Amirmounin Hospital in Rasht

Design

In this study, 74 patients with chronic rhinosinusitis having inclusion criteria who were referred to Amirmounin Hospital in Rasht are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

In this study, 74 patients referring to Amirmounin Hospital in Rasht are evaluated by blindfolded randomized clinical trial method. Sampling is performed by Balanced Block Randomization method. The data collection tool is information collection (questionnaire) that includes demographic data of patients, SNOT-22 questionnaire before and after treatment and possible complications. First examination of the patients will be done one week later and a second examination two weeks and a third examination three weeks after the start of treatment by the otolaryngologist, without knowing the patients are in which group, and the effect of treatment and possible side effects of drug use will be recorded.

Participants/Inclusion and exclusion criteria

including criteria: age above 18; having a minimum reading and writing literacy; affected by chronic rhinosinusitis according to the diagnosis of otolaryngologist; Exclusion Criteria: Pregnancy; History of sinus and nasal surgery; Usage corticosteroid drugs continuously and daily; Immunocompromised Disease; Nasal polyps; Lund-Mackay scores above 14 in sinus CT scan; Affected by chronic rhinosinusitis according to the diagnosis of otolaryngologist;

Intervention groups

A group receiving chamomile drop The group receiving

the placebo (drops of sesame seed oil)

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080831001138N27**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

Registration date

2018-05-09, 1397/02/19

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-22, 1396/12/03

Expected recruitment end date

2018-08-20, 1397/05/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Matricaria Chamomilla on Quality of Life in Patients with Chronic Rhinosinusitis Referred to Amirmounin Hospital in Rasht

Public title
Effect of Matricaria Chamomilla on Quality of Life in Patients with Chronic Rhinosinusitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old Having at least reading and writing skills Having chronic rhinosinusitis according to the diagnosis of ENT
Exclusion criteria:
Pregnancy History of sinus and nasal surgery Usage of corticosteroid drugs continuously and daily History of nasal polyp Lund-Mackay scores above 14 in sinus CT Rhinosinusitis Chronic exacerbation requires antibiotics History of any sensitivity to chamomile or its compounds Usage of drugs such as ciclosporin, aspirin, warfarin and heparin

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this way at first, before the start of the study, the Random Allocation software gives a list of random numbers that is evenly divided into two groups A and B to a third party, each of them in separate closed envelopes according to the list. If the patient is referred to and qualified, one of the envelopes is given to the patient according to the number and after filling the forms, the envelope is opened and the patient is placed in one of the groups and receives the corresponding medication. Patients will not inform about the received medication.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to maintain blindfolded of the study, both patients and researchers associated with patients will be unaware of the patient's drug intake (in the clinic, one researcher will distribute and record the drug to the

patient, and the other researcher will evaluate the patients. Medications will look quite similar in shape, color and size

Placebo
Used

Assignment
Parallel

Other design features
The clinical trial has two groups of cases and controls

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

vice-chancellor for Research Building, opposite of Sepah Bank, Shahid Beheshti Blvd

City

Rasht

Province

Guilan

Postal code

4139637459

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.GUMS.REC.1396.513

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Quality of life

Timepoint

Before the treatment, the first week, second week, third week

Method of measurement

Information obtained from the Sino-Nasal Outcome Test (SNOT-22) Questionnaire and biographies

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, chamomile extract was prepared by maceration method. Patients use 3 drops of the extract in each nostril after washing each nostril with 10 cc normal saline three times a day

Category

Treatment - Drugs

2

Description

Control group: washes the nose with 10 cc normal saline in each nostril three times a day then uses sesame seed oil as a placebo and three drops per nostril. All patients will be taught how to properly use drug and nasal washing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Shadman Nemati

Street address

Amiralmomenin Hospital, 17 Shahrivar Ave, Emam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Susan Komaee

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Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building, Rasht,

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

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Msc
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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