

# 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

##### City

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##### Province

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##### Postal code

4139637459

##### Phone

+98 13 3322 5242

##### Email

drshadmannemati\_ent@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Susan Komaee

##### Street address

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

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#### Province

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+98 13 3333 0959

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komaikoma@gums.ac.ir

#### 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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Amiralamomenin Hospital, 17 Shahrivar St

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Nezamdoust  
**Position**  
Msc  
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Master  
**Other areas of specialty/work**

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Guilan  
**Postal code**  
4139637459  
**Phone**  
+98 13 3322 5242  
**Email**  
fatemeh\_nezamdoust@yahoo.com

## 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