Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effects of topical application of micro emulsion prepared with Flax seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of rhino sinus cavity

Protocol summary

Study aim
Evaluation of the effects of topical application of micro emulsion prepared with flax seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of rhino sinus cavity.

Design
Clinical trial with control group and two intervention groups 1 and 2, three blind strains, non-randomized, phase 2-3, on 99 patients, uses the Covariate Adaptive Randomization (CAR) method to distribute confounding variables to the study groups.

Settings and conduct
The research is will perform in the hospitals clinic of Alborz University of Medical Sciences. After taking a history, the ENT specialist examines the patients and selects the desired samples in case of a definite diagnosis of Rhinosinusitis. After introducing and obtaining consent according to the CAR method, patients are placed in one of the three intervention groups and patients are evaluated in several stages. The letters A and B are used on the drugs, so the analyzer, patients and physician are not aware of the treatment method.

Participants/Inclusion and exclusion criteria
Inclusion criteria include all rhinosinusitis patients over 15 years of age and under 60 years of age, lack of sensitivity to herbal medicines and no use of anti-inflammatory and antimicrobial drugs during the last week ,also Rhinosinusitis patients with specific underlying diseases and Coronavirus involvement are not included in the study.

Intervention groups
Patients are intervened in three groups. In the control group, patients are treated with conventional oral tablets. In intervention group 1 Patients are treated with a topical solution containing micro emulsion made with flaxseed oil with conventional oral tablets. In intervention group 2 patients are treated with topical solution containing micro emulsion of flaxseed oil.

Main outcome variables
Inflammation of the mucosa of the Rhino sinus cavity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210421051030N1**
Registration date: **2021-08-13, 1400/05/22**
Registration timing: **prospective**

Last update: **2021-08-13, 1400/05/22**
Update count: **0**

Registration date
2021-08-13, 1400/05/22

Registrant information

Name
Behnam Mokri Savojbolaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 0000 0000

Email address
bms1909@iran.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-14, 1400/05/23

Expected recruitment end date
2021-08-20, 1400/05/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of topical application of micro emulsion prepared with Flax seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of rhino sinus cavity

Public title
Evaluation of the effects of solution made with flax seed oil in the treatment of rhinosinusitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All Rhinosinusitis patients over 15 years of age and under 60 years of age Not used immunosuppressive and antibiotics drugs during the last week Not allergic to herbal medicines and topical products No systemic diseases involving the Nasal cavity and Sinuses
Exclusion criteria:
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
the researcher In order to blind the research for the patients and the treating physician, has prepared both samples of the drug and placebo in the same form so that they are not aware of the type of drug and placebo treatment. Sprays containing flaxseed oil micro emulsion and spray containing normal isotonic saline (placebo) in similar pumped bottles were marked with A and B marks, respectively. Also, oral antibiotic-antihistamine tablets and placebo tablets with A and B marks were placed in similar cans, respectively. The project clinical assistant then delivers the sprays and tablets, pre-marked A and B, based on the group that the patient has been categorized by sampling method. Also, the collected data with the same abbreviations A and B are delivered to the analyzer to be realized in the third strain of blinding.
Placebo
Used
Assignment
Factorial
Other design features
Since the present study includes confounding variables including age, sex and anatomical anomalies, Covariate Adaptive Randomization (CAR) sampling method will be used to distribute and randomly assign patients with different confounders to intervention and control groups. In this method, after placing the first, second and third samples in each of the groups, the researcher places the next samples in the study groups based on the designed table, including three columns of confounder type factor and three rows of control and intervention groups. also adaptive (distribution) means distribution based on the type and number of distorters, which is done with the help of the above method.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Deputy of Research and Technology, Saffarian Alley, 45 meters of Golshahr
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2021-06-19, 1400/03/29
Ethics committee reference number
IR.ABZUMS.REC.1400.108

Health conditions studied

1

Description of health condition studied
Rhinitis
ICD-10 code
J30.9
ICD-10 code description
Allergic rhinitis, unspecified

2

Description of health condition studied
Sinusitis
ICD-10 code
J01.9
ICD-10 code description
Acute sinusitis, unspecified

Primary outcomes

1

Description
Inflammation of the mucosa of the rhino sinus cavity
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
headache
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

2

Description
Pressure and capillaries (the nose and paranasal sinuses)
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

3

Description
Sputum secretions
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

4

Description
Itching and runny nose
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

5

Description
Congestion and olfactory disorder
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

6

Description
Fever, cough and phlegm
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

7

Description
Swelling of the mucosa
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

8

Description
Redness of the mucosa
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

9

Description
Mucosal lesions
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

10

Description
Mucosal ulcers
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

Intervention groups

1

Description
Control group: Patients are treated with oral tablets (single dose of co amoxiclav 325 mg per day in bacterial rhinosinusitis and fexofenadine 180 in allergic rhinosinusitis). They also receive a solution containing normal saline isotonic as a placebo.
Category
Treatment - Drugs

2

Description
Intervention group 1: Patients are treated with a topical solution containing a micro emulsion prepared with flaxseed oil plus an oral tablet (single dose of co amoxiclav 325 mg in bacterial rhinosinusitis and fexofenadine 180 in allergic rhinosinusitis).
Category

Treatment - Drugs

3

Description
Intervention group 2: Patients are treated with a topical solution containing flax seed oil micro emulsion and placebo oral tablets.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ẹmam Ali Hospital
Full name of responsible person
Nasim Mirzaei
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Vali-e-Asr st. ,Three ways Resalat (formerly Azimiyeh)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Deputy of Reserch and Technology, Saffaritan alley, 45 meters of golshahr
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
BMS Science and Research group
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Behnam Mokri Savojbolaghi
Position
Clerk
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Person responsible for updating data

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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