

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Damprly herbal drops for the treatment of sinusitis patients with acute sinusitis

#### Protocol summary

##### Summary

1) Objective: Patients with sinusitis in many parts of the world, especially in cold regions there. There is no specific medication for treatment. Antibiotics used in treatment only. A drug with the least side effects and quite naturally we decided to treat this condition with very low cost and ease of use with the lack of treatment resistance in our body. 2) Design: Drop Damperly natural medicines derived from medicinal herbs such as black seed, rosemary and olive oil, which has antibacterial and antimicrobial activity and causes dilation of the arteries, congestion, sputum collection and disposal of infection and eventually drain the sinuses of pathogens is causing. 3) How to do: to treat patients randomly selected from patients referred to health centers and to get informed consent to be enrolled. This Damperly loved ones or drop or get it as a completely randomized placebo for 30 days and one day they use only a drop in the nose. 4) Participants: Study inclusion criteria will be as follows: 1. the patient is not under 7 years. 2. there is no history of certain diseases. 3. The patient is not pregnant. 4. The patient is not breast feeding. Exclusion criteria were studies will be as follows: 1. self-satisfaction. 2-allergy herbal medicine Sign Dameprly sensitive type. 5)routine treatment of sinusitis, including antibiotic Co-amoxiclav (if the sensitivity of Cefixime), serum washing (2-3 times a day) and Fluticasone spray is carried out. 6) The main outcome variables: After two weeks of receiving medications based on major and minor symptoms of sinusitis was examined and trend analysis of the notes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122131510N1**

Registration date: **2017-01-16, 1395/10/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-16, 1395/10/27

##### Registrant information

###### Name

Mahmud Khorushy

###### Name of organization / entity

iranian academic center for education, culture and research-Ardabil Branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3374 9503

###### Email address

sec.ar@acecr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iranian Academic Center for Education, Culture and Research, Ardabil branch

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Damprly herbal drops for the treatment of sinusitis patients with acute sinusitis

##### Public title

The effect of Damperli herbal drop on Sinusitis

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Study inclusion criteria will be as follows: 1. the patient is not under 7 years. 2. there is no history of certain diseases. 3. The patient is not pregnant. 4. The patient is not breast feeding. Exclusion criteria were studies will be as follows: 1- self-satisfaction. 2-allergy Damperly herbal drops sensitive type.

### **Age**

From **7 years** old to **90 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ardabil University of Medical Sciences and Health Services

##### **Street address**

Ardabil University of Medical Sciences, Daneshgah street.

##### **City**

Ardabil

##### **Postal code**

##### **Approval date**

2016-12-21, 1395/10/01

##### **Ethics committee reference number**

IR.ARUMS.REC.1395.97

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Acute sinusitis

#### **ICD-10 code**

J01

### **ICD-10 code description**

Acute sinusitis

## **Primary outcomes**

### 1

#### **Description**

Facial pain / pressure

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 2

#### **Description**

Facial congestion / fullness

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 3

#### **Description**

Nasal obstruction / blockage

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 4

#### **Description**

Nasal discharge / purulence, discolored posterior drainage

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 5

#### **Description**

Hyposmia / anosmia

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 6

#### **Description**

Purulence on nasal examination

#### **Timepoint**

Before and two weeks after the intervention

#### **Method of measurement**

Find out - Photos - CT

### 7

#### **Description**

Fever (acute rhinosinusitis only)

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**Secondary outcomes**

**1**

**Description**

Headache

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**2**

**Description**

Fever (nonacute rhinosinusitis)

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**3**

**Description**

Halitosis

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**4**

**Description**

Dental pain

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**5**

**Description**

Cough

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**6**

**Description**

Ear pain / pressure / fullness

**Timepoint**

Before and two weeks after the intervention

**Method of measurement**

Find out - Photos - CT

**Intervention groups**

**1**

**Description**

Controls: placebo drops of distilled water or NaCl which will be used as a drop Damply consumed. routine treatment of sinusitis, including antibiotic Co-amoxiclav (if the sensitivity of Cefixime), serum washing (2-3 times a day) and Fluticasone spray is carried out.

**Category**

Placebo

**2**

**Description**

Invention: drop Damply be used. routine treatment of sinusitis, including antibiotic Co-amoxiclav (if the sensitivity of Cefixime), serum washing (2-3 times a day) and Fluticasone spray is carried out.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sabalan hospital

**Full name of responsible person**

Dr. Rauf Molla Javadi

**Street address**

Vahdat sq.

**City**

Ardabil

**2**

**Recruitment center**

**Name of recruitment center**

Fatemi hospital

**Full name of responsible person**

Dr. Soureh Allaf Akbari

**Street address**

Sharyati sq.

**City**

Ardabil

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

iranian academic center for education, culture and research, ardabil branch

**Full name of responsible person**

Dr. Ramez Nasiri Saleh

**Street address**

Shafa Sq., Karshenasan

**City**

Ardabil

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

iranian academic center for education, culture and research, ardabil branch

**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**

S. W. A. Co.

**Full name of responsible person**

Mahmud Khorushy

**Position**

Chairman of the Board

**Other areas of specialty/work**

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**Web page address**

**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

ENT specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Full name of responsible person**

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**Position**

member

**Other areas of specialty/work**

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www.jdard.ac.ir

**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*