

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Effect of therapeutic pulsed ultrasound on severity of symptoms of patients with chronic rhino-sinusitis with and without polyposis- A randomized clinical trial

#### Protocol summary

##### Study aim

The effect of ultrasound therapy on the symptoms of chronic rhinosinusitis

##### Design

Clinical trial with control group, single blind, randomized, on the 44 patients. Randomization is simple by random number generator

##### Settings and conduct

This study is about the effects of ultrasound therapy on chronic rhinosinusitis. The site of this study is in the ENT clinic of Amir Alam Hospital. Patients are confirmed by their ENT specialist for chronic sinusitis and then treated with ultrasound with personal consent. According to the procedure, ultrasound therapy is applied to the frontal and maxillary sinuses. The treatment is three days a week. Patients are blind and do not know what group they are in. The ultrasonic light in both groups is a sign of its apparent brightness, but in the control group there is no output.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. No malignant tumor on the head and face 2. Has comprehensible literacy and verbal power 3. Ability to recognize and comprehend at the natural level  
exclusion criteria: 1. Having cold during treatment 2. Acute recurrence of rhinosinusitis

##### Intervention groups

Intervention group: Participants in this group have chronic rhino sinusitis and are treated by ultrasound therapy in ten sessions in the frontal and maxillary sinuses to reduce the symptoms of chronic sinusitis.  
Control group: People in this group also suffer from chronic sinusitis, and this group is apparently treated with ultrasound therapy, and only the ultrasound light is a sign that the device is visible, but they do not receive ultrasound therapy intervention.

##### Main outcome variables

Treatment of sinusitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150915024031N2**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

##### Registration date

2021-03-17, 1399/12/27

##### Registrant information

##### Name

Mojtaba Mohammadi Ardehali

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6670 3037

##### Email address

mohamadm@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| empty                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Scientific title</b>                       | Effect of therapeutic pulsed ultrasound on severity of symptoms of patients with chronic rhino-sinusitis with and without polyposis- A randomized clinical trial                                                                                                                                                                                                                                                                                   |
| <b>Public title</b>                           | "Effect of therapeutic ultrasound on chronic rhino sinusitis"                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Purpose</b>                                | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Inclusion/Exclusion criteria</b>           |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Inclusion criteria:</b>                    | No malignant tumor on the head and face Has comprehensible literacy and verbal power Ability to recognize and comprehend at the natural level                                                                                                                                                                                                                                                                                                      |
| <b>Exclusion criteria:</b>                    | Having cold during treatment Acute recurrence of rhinosinusitis                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Age</b>                                    | From <b>20 years</b> old to <b>50 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Participant</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sample size</b>                            | Target sample size: <b>44</b>                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Randomization description</b>              | Randomization is based on the role of random allocation. In this method, 22 letters A representing the intervention group and 22 letters B representing the control group are placed in a container. Then a letter is accidentally removed from the container. If the letter A is, the person goes to the intervention group and if it is the letter B, the person goes to the control group. Similarly, we divide 44 people into 2 random groups. |
| <b>Blinding (investigator's opinion)</b>      | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Blinding description</b>                   | Patients participating in this study are blind. At the beginning of treatment, patients in the control group are not treated with ultrasound and only the ultrasound light is on as visual feedback. And the same light is on in the intervention group, and neither group is aware of the device output.                                                                                                                                          |
| <b>Placebo</b>                                | Used                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran university of medical sciences

##### Street address

Keshavarz Blvd., Ghods St., Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Approval date

2020-11-09, 1399/08/19

##### Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1399.029

## Health conditions studied

### 1

#### Description of health condition studied

Chronic rhino sinusitis

#### ICD-10 code

J32

#### ICD-10 code description

Chronic sinusitis

## Primary outcomes

### 1

#### Description

Score in 20 item questionnaire SinoNasal outcome Test-20 (SNOT-20)

#### Timepoint

first and second session

#### Method of measurement

SNOT-20 questioner

## Secondary outcomes

### 1

#### Description

Lund Kennedy endoscopic scale

#### Timepoint

First and last session

#### Method of measurement

Lund Kennedy endoscopic scale

### 2

#### Description

Lund Mackay scale

**Timepoint**

First and last session

**Method of measurement**

Lund Mackay scale

**Intervention groups****1****Description**

The intervention group receives ,the Japanese ITO-750 model, 3 days a week with ultrasound therapy in the maxillary and frontal sinuses. The frequency and intensity used for each frontal sinus is 3 MHz and 0.5 watts per square centimeter and for each maxillary sinus is 1 MHz and 1 watt per square centimeter. The total treatment time is 18 minutes, which is 4 minutes for each frontal sinus and 5 minutes for each maxillary sinus. MHz and 1 watt per square centimeter for each maxillary sinus. The total treatment time is 18 minutes, which is 4 minutes for each frontal sinus and 5 minutes for each maxillary sinus.

**Category**

Rehabilitation

**2****Description**

Control group: Participants in the control group who, like the intervention group, have chronic sinusitis. The procedure is relatively similar to that of the intervention group, with the same device as the ITO-750 model made in Japan, and they receive physical treatment three days a week. The difference is that in this group, no ultrasound waves are emitted through the device, but they are told that the bright light of the device indicates the penetration of waves in the body.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amiralam hospital ENT clinic

**Full name of responsible person**

Mojtaba Mohammadi Ardehali

**Street address**

Enghelsb Ave, norh Sadi, Amiralam hospital ENT clinic

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mohamadm@sina.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

MohammadAli Sahraeian

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vcr@tums.ac.ir

**Grant name**

-

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mojtaba Mohammadi Ardehali

**Position**

professor , ENTspecilalist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mojtaba Mohammadi Ardehali  
**Position**  
ENT specialist, Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mojtaba Mohammadi Ardehali  
**Position**

ENT specialist, Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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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