Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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

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

Public title
"Effect of therapeutic ultrasound on chronic rhino sinusitis"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No malignant tumor on the head and face Has comprehensible literacy and verbal power Ability to recognize and comprehend at the natural level
Exclusion criteria:
Having cold during treatment Acute recurrence of rhinosinusitis
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Single blinded
Blinding description
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.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

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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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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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

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Position
ENTspecialist, Professor
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Specialist
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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