

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of therapeutic pulsed ultrasound on smell disorder in adults with chronic rhinoisinitis

Protocol summary

Summary

Objective: The effect of Therapeutic pulsed ultrasound in adult with a rhinosinitis! Design: Non randomised, Single blind, Without control group, Without placebo, For one stage clinical trial! Setting and conduct: The patient was treat in 10 sessions! Inclusion criteria: 1- Age 20 -50 years, 2- Without face surgery and face malignancy tumor, 3- Understanding literacy and verbal power! Exclusion criteria: 1- Cold-infection in the course of treatment! Intervention: Pulsed ultrasound! Main outcome measures (variables): The sinusitis symptom severity questionnaire and smell test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050533821N1**
Registration date: **2017-09-04, 1396/06/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

Atieh Nazem

Name of organization / entity

Faculty of Rehabilitation in Tehran University of Medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-06-16, 1396/03/26

Expected recruitment end date

2017-07-16, 1396/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of therapeutic pulsed ultrasound on smell disorder in adults with chronic rhinoisinitis

Public title

The effect of therapeutic ultrasound on smell disorder with chronic rhinoisinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 50 years! with a Chronic rhinosinitis (diagnosis of a especial physician! clinical finding CT-scan and having symptoms such as posterior throat, cough, headache when bending forward, feeling full pressure of face and smell disorder)! No history of surgery in the nose and sinuses! Not having a malignant tumor on the face and head and mental disorders (Hallucination)! Understanding literacy and verbal power! Ability to recognize and understand at normal level! Exclusion criteria: Cold-infection in the course of treatment! Acute recurrence of rhinosinitis.

Age

From **75 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Tehran University of Medical Sciences, Qods ST, Keshavarz BLV

City

Tehran

Postal code

Approval date

2017-04-15, 1396/01/26

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2079

Health conditions studied

1

Description of health condition studied

CHRONIC RHINOSINUSITIS

ICD-10 code

J32.9

ICD-10 code description

•Inflammation of the paranasal sinuses that typically lasts beyond eight weeks. It is caused by infections, allergies, and the presence of sinus polyps or deviated septum. Signs and symptoms include headache, nasal discharge, swelling in the face, dizziness

Primary outcomes

1

Description

Smell disorder

Timepoint

Ten days and one month after treatment

Method of measurement

Smell identification test

2

Description

Severity of chronic rhinosinusitis symptoms

Timepoint

Ten session and one month later

Method of measurement

SNOT-20 valid questionnaire

Secondary outcomes

1

Description

Gender

Timepoint

First session

Method of measurement

Based on apparent phenotype

2

Description

History of disease

Timepoint

First session

Method of measurement

Ask the patient

3

Description

Affected sinuses

Timepoint

First session

Method of measurement

CT-scan

4

Description

Age

Timepoint

First session

Method of measurement

Birth certificate information

Intervention groups

1

Description

In treatment group, intervention was used by ultrasonic machine, ITO 750 model

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation of Tehran university of Medical Sciences

Full name of responsible person

Doctor Sofia Naghdi (Associate Professor)

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Faculty of Rehabilitation of Tehran University of Medical Sciences, Pich-e-shemiran ST, Enghelab AV, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice chancellor for research of Tehran University of Medical Sciences

Street address

Tehran university of medical science, Qods ST, Keshavarz BLV

City

Tehran

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

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

Faculty of Rehabilitation of Tehran University of Medical Science

Full name of responsible person

Atieh Nazem

Position

Master candidate

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Rehabilitation of Tehran University of Medical Sciences

Full name of responsible person

Sofia Naghdi

Position

Associate Professor

Other areas of specialty/work

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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