

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

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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)

**Street address**

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****Street address**

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## Person responsible for updating data

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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*