

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Consideration of pulsed and continuous ultrasound mechanism(s) in culture and real time PCR data of staphylococcus and streptococcus in chronic rhinosinusitis patients.

Protocol summary

Study aim

Inspection of chronic rhinosinusitis patient's sinuses secretion before and after ultrasound usage.

Design

The study is double blind randomized clinical trial. Sampling is done randomly among patients with chronic rhinosinusitis referring to treatment centers affiliated and non-affiliated to Iran University of Medical Sciences by an otolaryngologist.

Settings and conduct

Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients enter the study based on CT scan image, the patients history and physical examination by the doctor. A patient is excluded if has sinus or nasal polyps or a deviated septum or has undertaken rhinoplasty. Other exclusion criteria include: diabetes, vasculitis, hepatics any type of malignancy in the skull and any immunodeficiency.

Intervention groups

Group 1: include chronic rhinosinusitis patients which 1 megahertz frequency pulsed ultrasound (1MHzPUS) will be used for them. Group 2: include chronic rhinosinusitis patients which 1 megahertz frequency continuous ultrasound (1MHzCUS) will be used for them. Group 3: include chronic rhinosinusitis patients which ultrasound therapy is not performed immediately for them but, based on the specialist idea, routine treatment or ultrasound therapy will be done 3 weeks after entering to the present study. Group 4: include of healthy subjects who are not suffering from chronic rhinosinusitis and have not had any type of the respiratory system surgery.

Main outcome variables

CT scan score; colony count; SNOT-20 score.

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20140810018754N8**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Javad Sarrafzadeh

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-07, 1397/04/16

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Consideration of pulsed and continuous ultrasound mechanism(s) in culture and real time PCR data of staphylococcus and streptococcus in chronic rhinosinusitis patients.

Public title
Effect of ultrasound on sinusitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Presence of secretions in maxillary and frontal sinus cavities based on CT scan. Secretions in the back of the throat or rhinorrhea for at least three months.
Exclusion criteria:
 Sinus or nasal polyps A deviated nasal septum
 Background of rhinoplasty Diabetes Vasculitis Hepatitis
 Any type of malignancy in the skull Any immunodeficiency

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants are classified in different groups after familiarization with execution of the present study and obtaining informed consent but they are not aware of which group they are in. The outcome evaluator is not aware of which patient is being studied in any of the present study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

5th floor, Iran University of Medical Sciences, Hemmat highway, between Sheikh Fazlollah Nuri and Chamran highways.

City

Tehran

Province

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Postal code

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Approval date

2016-12-13, 1395/09/23

Ethics committee reference number

ir.iums.rec1395.9211342214

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

Primary outcomes

1

Description

Colony count (measurement of the growth of bacteria in a sample that has been cultured for 24 to 48 hours).

Timepoint

Before and after intervention

Method of measurement

Microscopic and real-time polymerase chain reaction (PCR) assays

2

Description

Type of microbe

Timepoint

Before and after intervention

Method of measurement

Microscopic and real-time polymerase chain reaction (PCR) assays

3

Description

Computed tomography (CT) scan score of Frontal and Maxillary sinuses

Timepoint

Before and after intervention

Method of measurement

Lund-Mackay method scoring

4**Description**

SNOT-20 test score (Sino-nasal Outcome Test-20)

Timepoint

Before and after intervention

Method of measurement

From 0 up to 100 score

Secondary outcomes

empty

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

First intervention group or group 1: include chronic rhinosinusitis patients which treat with a ultrasound device on Frontal and Maxilla sinuses and parameters of: 1 megahertz frequency pulsed ultrasound (1MHzPUS) with 10 percent duty cycle, 4 centimeter per second the probe velocity, 1 watt per centimeters square intensity for Maxillary sinus and 0.5 watt per centimeters square intensity for frontal sinuses for 10 sessions.

Category

Treatment - Other

2**Description**

Second intervention group or group 2: include chronic rhinosinusitis patients which treat with a ultrasound device on Frontal and Maxilla sinuses and parameters of: 1 megahertz frequency continuous ultrasound (1MHzCUS) with 10 percent duty cycle, 4 centimeter per second the probe velocity, 1 watt per centimeters square intensity for Maxillary sinus and 0.5 watt per centimeters square intensity for frontal sinuses for 10 sessions.

Category

Treatment - Other

3**Description**

Control group or group 3: include chronic rhinosinusitis patients which ultrasound therapy is not performed for them. Data from this group will compare with group 1 and group 2 data and will use for analyzing the effects of ultrasound therapy.

Category

Treatment - Other

4**Description**

Healthy subjects group or group 4: include subjects

without chronic rhinosinusitis. Data from this group will consider as normal values for comparing with treatment groups of the present study.

Category

Treatment - Other

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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

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

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Full name of responsible person

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Javad Sarrafzadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data or results of the present study will be presented

in an article or some articles that will be published after completing the study.

When the data will become available and for how long

After completing the present study and publishing the resulting article or articles.

To whom data/document is available

All researchers in the field of the present study.

Under which criteria data/document could be used

With the same goal as the present study and with mention of the present study as the reference. All

intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

From where data/document is obtainable

The corresponding author of the article or articles derived from this study.

What processes are involved for a request to access data/document

Written request from the author responsible for the present review after the publication of the resulting article or articles.

Comments