

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effect of low level laser and pulsed ultrasound on sinus mucus inflammation using fractional exhaled nitric oxide in patients with chronic rhinosinusitis (CRS)

Protocol summary

Study aim

Comparing the effect of low level laser (LLL) and pulsed ultrasound (PUS) on sinus mucus inflammation using fractional exhaled nitric oxide (FeNo) in patients with chronic rhinosinusitis (CRS)

Design

Randomize clinical trial, single blind with parallel groups and one-month follow-up, randomization by Stratified Permuted Block method. The sample size was obtained by using G-power software in each group of 20 people

Settings and conduct

The study will be conducted on 40 patients with CRS who have referred to the Rehabilitation School of Tehran University of Medical Sciences. Patients with inclusion criteria will be randomly divided to one of the two groups of PUS and LLL by selecting a sealed envelope by the clinic secretary after the initial evaluation. 5 treatment sessions are done every day. The research is done single blind and the evaluator will be unaware of the type of treatment of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 years, no facial surgery and malignant facial tumor, no polyps, asthma and respiratory diseases. Exclusion criteria: acute recurrent of rhinosinusitis during treatment

Intervention groups

Five sessions of PUS treatment are performed daily on the affected sinuses in the patients of the first intervention group and five sessions of LLL treatment are performed on the affected sinuses in the patients of the second intervention group. This study does not have a control group.

Main outcome variables

SNOT22 questionnaire FeNo test Scoring the symptoms based on the sinus scan stereotype

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230805059035N1**

Registration date: **2023-09-15, 1402/06/24**

Registration timing: **prospective**

Last update: **2023-09-15, 1402/06/24**

Update count: **0**

Registration date

2023-09-15, 1402/06/24

Registrant information

Name

Mina Kashi Alashti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7703 2824

Email address

kashialashtimina69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of low level laser and pulsed ultrasound on sinus mucus inflammation using fractional exhaled nitric oxide in patients with chronic rhinosinusitis (CRS)

Public title

Comparing the effect of laser and ultrasound on sinus mucus inflammation in patients with chronic rhinosinusitis (CRS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic rhinosinusitis; The duration of infection is between 3 months and a maximum of 5 years

Exclusion criteria:

Not having polyp and sinus retention cyst No history of facial surgery No malignant lesions in the head and neck area Not having asthma and respiratory diseases

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization in this study will be by the Stratified Permuted Block Randomization method, in which people are divided into two groups (ultrasound treatment group and laser treatment group) after meeting the conditions for entering the study. For this purpose, first, by Random Allocation computer software (version 1.1, Isfahan University of Medical Sciences, Iran), a random order of two letters A (ultrasound treatment) and B (laser treatment) in blocks with random numbers of 4 and 6 (for example ABBA and ABAABB are made. Then the blocks are hidden by non-transparent envelopes. In order to minimize the selection bias and ensure the concealment of the allocation of people in the groups, the randomization process is done by a person who is not in any of the other stages of the research. In this way, patients are randomly placed in one of the two groups (pulsed ultrasound treatment or low power laser treatment).

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator will be unaware of the type of treatment of the patients.

Placebo

Not 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

School of Rehabilitation of Tehran University of Medical Sciences, Pich Shemiran, Islamic Revolution St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

65111-11489

Approval date

2023-08-16, 1402/05/25

Ethics committee reference number

IR.TUMS.FNM.REC.1402.119

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

Exhaled nitric oxide level

Timepoint

Before the start of the intervention, immediately after the intervention and one month after the intervention

Method of measurement

Fractional exhaled nitric oxide test with nitric oxide analyzer

2

Description

CT scan score

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Seeing the CT scan stereotype

3

Description

Total score of clinical symptoms

Timepoint

Before the start of the intervention, immediately after the intervention and one month after the intervention

Method of measurement

Sinonasal Outcome Test 22 (SNOT 22) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first intervention group, ITO 750 pulsed ultrasound therapy is used. The patient is treated with pulsed ultrasound for 5 sessions every day. In each treatment session, each maxillary sinus for 5 minutes with a dose of 1 w/cm² and each frontal sinus for 4 minutes with a dose of 0.5 w/cm², with an applicator with a cross section of 1 cm² and with circular movements is treated on the surface anatomy of the corresponding sinus. The frequency used in all treatment sessions will be 1MHz and the pulse time used will be 1ms and the pulse interval will be 9ms.

Category

Treatment - Other

2

Description

Intervention group: In the second intervention group, a low-level Enraf 476 laser is used. Laser treatment is done for 5 sessions every day. The surface of each sinus is divided into 6 points and each point is treated for 33 seconds with an intensity of 1 joule with a point applicator. In total, in each treatment session, each involved sinus is exposed to laser radiation for 198 seconds. The laser used will be a continuous-type gallium aluminum arsenide diode, with a wavelength of 830 nm, and a power of 30 milliwatts.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Dr. Nouredin Nakhostin Ansari

Street address

School of Rehabilitation, Tehran University of Medical Sciences, Pich Shemiran, Islamic Revolution St, Tehran

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 7753 3939

Email

nnansari40@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

Street address

Tehran University of Medical Sciences, Corner of Qods Street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

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

Mina Kashi Alashti

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapist

Street address

School of Rehabilitation, Pich Shemiran, Islamic Revolution St, Tehran

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 7753 3939

Fax

+98 21 7753 4133

Email

nnansari40@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Nouredin Nakhostin Ansari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation of Tehran University of Medical Sciences, Pich Shemiran, Islamic Revolution St, Tehran

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 7753 3939

Email

nnansari40@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mina Kashi Alashti

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Pich Shemiran, Islamic Revolution St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 7753 3939

Fax

Email

kashialashtimina69@gmail.com

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

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

Yes - There is 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

Title and more details about the data/document

The raw data of the research and its analysis will be provided to the researchers upon their request.

When the data will become available and for how long

After the publication of the articles resulting from the research.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

The data is provided to other researchers only to study and check the treatment results.

From where data/document is obtainable

Department of Physiotherapy, School of Rehabilitation of Tehran University of Medical Sciences, Islamic Revolution St, Pich Shemiran, Dr.Nouredin Nakhostin Ansari, 09122979309, nakhostin@sina.tums.ac.ir

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

By sending an official university email to the corresponding author, Dr. Nooruddin Ansari (nakhostin@sina.tums.ac.ir) and requesting documents, a response will be provided as soon as possible.

Comments