

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Title : Effects of pulsed ultrasound on smell disorder in COVID-19

Protocol summary

Study aim

Investigation of effect of pulsed ultrasound on smell disorder in recovered patients of COVID 19 getting better of variable of smell disorder in recovered patients of COVID 19 based on IRAN- SIT score

Design

one intervention group and one controlled group and 15 patients in each group, single blinded, randomized

Settings and conduct

Tehran university medical science , war science center

Participants/Inclusion and exclusion criteria

age range:18 to 65 pass of 3 month of recovery or COVID 19

Intervention groups

Intervention group: recovered patients of COVID19 between 18 to 65 years old that intervened by continues ultrasound Controlled group: recovered patients of COVID19 between 18 to 65 years old that don't intervene treatment and pelacebo

Main outcome variables

Smell disorder Tthreshold of smell sense

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054434N1**

Registration date: **2022-05-15, 1401/02/25**

Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**

Update count: **0**

Registration date

2022-05-15, 1401/02/25

Registrant information

Name

Narjes Feizabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 7019

Email address

feizabadi.na@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Title : Effects of pulsed ultrasound on smell disorder in COVID-19

Public title

Title : Effects of pulsed ultrasound on smell disorder in COVID-19

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

remaining STD 3 month after recovery of COVID 19

Exclusion criteria:

malignancy in skull

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by selection chancing. Performing of randomization by clinician and selection of chancing by patient without patient's awareness about being in which group. randomization chancing are After determination of total number of participants that is 30 numbers, 15 buoys showed by A and 15 buoys showed by B are poured in a dish and pulled out via randomization and without replacement and this series is recorded. when a participant select a chance , in closed and dark packets which are gotten clinician, it will be adapted with the series then the group of participant will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer doesn't know about meaning of A& B and groups. because of the reason he or she is blinded about groups and study. single blind via analyzer.

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

No. 7,Khayam Ended, Motalebinejad, West Akhlaghy kolahdooz Ave, Shemiranat Town

City

Tehran

Province

Tehran

Postal code

1939767773

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1520

Health conditions studied

1

Description of health condition studied

Smell disorder remained by COVID19

ICD-10 code

R43.0

ICD-10 code description

Anosmia

Primary outcomes

1

Description

smell disorder

Timepoint

first and end of intervention and follow

Method of measurement

IRAN-SIT Score

2

Description

threshold of smell sense

Timepoint

first and end of intervention and follow

Method of measurement

botanical test score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: treatment by continues ultrasound in wall airways with 1 Watt/Cm2 intensity and 4 minutes duration in each session in total 10 session

Category

Treatment - Other

2

Description

Control group: without treatment intervention, without placebo

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

War Research Center

Full name of responsible person

Feizabadi Narjes

Street address

No. 8 Khayam Ended , Motalebinejad West Akhlaghy
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Email

FEIZABADI.NA@IUMS.AC.IR

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraeeyan Mohamadali: Research Assistant of
Tehran University of Medical Science

Street address

Poursina , Ghods street, Enghelab, Tehran Town

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feizabadi.na@iums.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

Feizabadi Narjes

Position

Consaltant

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Position

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Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

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Other areas of specialty/work

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all data for all patients and for both variables record exactly

When the data will become available and for how long

6 month after publication

To whom data/document is available

just for academic persons

Under which criteria data/document could be used

for use in clinical trial

From where data/document is obtainable

to corresponding author's email

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

email

Comments