

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of vanilla essential oil with eucalyptus essential oil on the return of olfactory sense in COVID-19 patients with olfactory dysfunction

Protocol summary

Study aim

Comparison effect of vanilla with eucalyptus essential oil on the return of sense of smell in patients with Covid -19 with olfactory sensory impairment

Design

Clinical trial with two intervention groups (vanilla group, eucalyptus group) and control group, with parallel groups, double-blind, phase 3 on 84 patients who were randomly assigned to one of the intervention and control groups using blocking. The list of blocks and their random order will be determined by the statistics consultant based on Proc PLAN in SAS software.

Settings and conduct

After obtaining a research license from Zanjan University of Medical Sciences and coordination with Kurdistan University of Medical Sciences, we will refer to covid - 19 outpatient clinics in Zanjan and Bijar Hospital to collect data. Patients with inclusion criteria after obtaining informed consent are randomly divided into three groups including vanilla group, eucalyptus group and control group. A questionnaire of demographic information and disease characteristics and quality of sense of smell for the samples will be completed before the intervention. The intervention groups will receive the intervention (olfactory stimulation) for one week. Samples in the control group will receive routine care. Then, one week and two weeks after the intervention, the olfactory quality questionnaire will be completed in all three groups. SPSS statistical software version 20 will be used for Statistical analysis of data and a significance level of less than 0.05 will be considered.

Participants/Inclusion and exclusion criteria

-Having informed consent - positive PCR test - They did not experience any loss of sense of smell or taste for at least 2 weeks before the first Covid-19 demonstrations began. - Non-smoker

Intervention groups

Vanilla group, eucalyptus group and control group

Main outcome variables

Intensity of the sense of smell

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050231N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

Mohamad ali yadegary

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

ma.yadegary@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-30, 1400/02/10

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vanilla essential oil with eucalyptus essential oil on the return of olfactory sense in COVID-19 patients with olfactory dysfunction

Public title

Comparison of the effect of vanilla essential oil with eucalyptus essential oil on the return of olfactory sense in COVID-19 patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent to participate in the study - Have a positive PCR test They did not experience any signs of decreased olfactory and taste sensation at least 2 weeks before the onset of the first Covid-19 demonstrations. -Living in the city Non-smoker

Exclusion criteria:

- People with certain underlying diseases (such as asthma and history of allergies, Parkinson's, Alzheimer's, severe eating disorders, acute rhinitis, acute sinusitis, nasal congestion, for example, after rhinoplasty, traumatic nerve damage and. Having other viral and bacterial infections at the same time as Covid-19 - People who deal with thick odors in their job, such as working with paint or acid.

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the available people, randomly blocked blocks with a volume of "6 random blocks" will be randomly assigned to one of the intervention and control groups, the list of blocks and their random order by the statistical consultant and based on Proc PLAN in software The SAS software will be identified and made available to the patient selector. In the proc command we will defined the total number of required samples, number of blocks, number of groups, code related to arm. so, output of SAS includes the code of participants in blocks with size 6, in each block, 2 samples regarding to each group are randomly distributed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the control group will receive a placebo. Statistical consultants are unaware of intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of zanjan university of medical sciences

Street address

Professor Yousef Sabouti Blvd., Zanjan University of Medical Sciences

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zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2021-04-24, 1400/02/04

Ethics committee reference number

IR.ZUMS.REC.1400.061

Health conditions studied**1****Description of health condition studied**

covid-19

ICD-10 code

U07.1

ICD-10 code description

Coronavirus infection, unspecified site (B34.2) Coronavirus as the cause of diseases classified to other chapters (B97.2) Severe acute respiratory syndrome [SARS], unspecified (U04.9)

Primary outcomes**1****Description**

The result of the olfactory test is reported as a number from zero to 24 and indicates the function of the sense of smell in the range of normal and mild normosemia, anosmia, hyposemia (microsaemia).

Timepoint

Before intervention, one week after intervention, two weeks after intervention

Method of measurement

University of Pennsylvania Odor Detection Test (UPSIT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group have olfactory stimulation (sniffing 100% pure eucalyptus essential oil from the French company seven star) in plastic perfume bottles of 2.5 ml with the label "Do not eat" How to use: irritating smell for a week, every day 6 times (within 4 hours) after washing your nose with saline 0.9 percent.

Category

Rehabilitation

2

Description

Intervention group 2: Patients in this group have olfactory stimulation (smelling 100% pure vanilla essential oil from the French company sevenstar) in 2.5 ml plastic perfume containers labeled "Do not eat" How to use: Odor stimulation will be done 6 times a day (4 hours apart) after rinsing your nose with 0.9% rinsing serum.

Category

Rehabilitation

3

Description

Control group: Patients in this group will receive placebo (plastic perfume containers containing 2.5 ml of water labeled "Do not eat" for 6 weeks (every 4 hours) after rinsing the nose with serum Wash percentage)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

covid-19 outpatient clinics in Bijar

Full name of responsible person

mohamad ali yadegari

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Kurdistan, Bijar, Shahid Rahmani Boulevard

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

alireza shoghli

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Grant name

Vice-Chancellor for Research and Technology of Zanjan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

35

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**

Zanjan University of Medical Sciences

Full name of responsible person

Mohamad ali Yadegary

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address**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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All study information except personal information of the participants

When the data will become available and for how**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Mohamad ali Yadegary

Position

Professor

Latest degree

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Other areas of specialty/work

Nursery

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long

A year after the publication

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

To extract more findings

From where data/document is obtainable

By e-mail after the permission of the University of Medical Sciences

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

Obtain permission from Zanzan University of Medical Sciences, email it to the person in charge of research, receive information

Comments