Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 24 3314 8241

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
City
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
Street address
Kurdistan, Bijar, Shahid Rahmani Boulevard
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2

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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
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

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 Zanjan University of Medical Sciences, email it to the person in charge of research, receive information

Comments