Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study of the effect of olfactory training and vitamin A in the olfactory loss of patients with covid-19.

Protocol summary

Study aim
Comparison of the therapeutic effect of vitamin A and olfactory rehabilitation in improving anosmia, hypovasemia in patients with COVID-19 disease

Design
This study is a controlled clinical trial study. Patients will be divided into three groups of 30 in a simple random method according to the table of random numbers.

Settings and conduct
This study is scheduled to be carried out in Baqiyatallah Hospital. In this study, 90 positive Covid patients with anosmia and hyposemia for more than 2 weeks and no change in patients' olfactory improvement will be included in the study.

Participants/Inclusion and exclusion criteria
Lack of underlying disease including: hypertension, hypo and hyperthyroidism, seizures, diabetes, asthma, Bell's palsy; Continuation of olfactory loss for more than two weeks

Intervention groups
The first group will be treated only with respiratory physiotherapy or olfactory rehabilitation for 12 weeks, in which we will provide an olfactory kit that includes 4 main scents (eucalyptus, lemon, rose and dianthus) and the patient You will be asked to inhale each scent twice a day for 10 seconds each time. The second group will be treated with vitamin A tablets (10,000 units per day) along with the olfactory rehabilitation method for 12 weeks. Patients in the third group (control) will be followed up for 12 weeks to record the time of this event in case of spontaneous anosmia and hypoxemia.

Main outcome variables
Odor detection: Measurements will be performed at time zero (before intervention) and 12 weeks (after intervention) using an olfactory kit

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210205050247N1**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**
Update count: **0**

Registration date
2021-02-13, 1399/11/25

Registrant information

Name
Abolfazl Taheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8216 2440

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abolfzl.taheri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-18, 1399/11/30

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of olfactory training and vitamin A in the olfactory loss of patients with covid-19.

Public title
The effect of olfactory training and vitamin A in the olfactory loss of patients with covid-19.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 65 No underlying disease including: hypertension, hypo and hyperthyroidism, seizures, diabetes, asthma, Bell's palsy Continuation of olfactory reduction for more than two weeks
Exclusion criteria:
Patient dissatisfaction Prolonged exposure to some chemicals agents (detergents) History of head trauma History of sinus surgery or septorhinoplasty, rhinoplasty, turbinectomy and radiation therapy Having neurodegenerative disease (Alzheimer's, Parkinson, MS, epilepsy, seizures) Having mental disorders (schizophrenia and depression) Having neuropsychiatric disorders (autism, Asperger's, lack of concentration and hyperactivity) History of repeated use of the following drugs:Metronidazole, benzocaine, clofibrate, amphotericin B, ampicillin, allopurinol, captopril, baclofen, codeine, carbamazepine and amphetamines.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into three groups of 30 in a simple random method according to the table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
In a double-blind study, both participants and researchers or outcome assessors are unaware of the allocation of 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 Baghiyyatollah University of Medical science
Street address
Sheikh bahaei, Molla-Sadra Avenue, Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2020-04-04, 1399/01/16
Ethics committee reference number
IR.BMSU.REC.1399.066

Health conditions studied

1

Description of health condition studied
olfactory loss
ICD-10 code
R43.8
ICD-10 code description
Other disturbances of smell and taste

Primary outcomes

1

Description
Smell Identification
Timepoint
The olfactory test is performed for 12 weeks, twice a day, each time inhaling each odor for 10 seconds.
Method of measurement
Aromatic kit that includes 4 main scents (eucalyptus, lemon, rose and Dianthus)

Secondary outcomes

1

Description
clinical recovery
Timepoint
For 12 weeks
Method of measurement
Clinical Global Impression Severity (CGI-S) Scale

2

Description
Olfactory Dysfunction Outcomes Rating (ODOR)
Timepoint
For 12 weeks
Method of measurement

Pre-test and post-test questionnaires will be filled in all three groups

Intervention groups

1

Description
Intervention group: This group will be treated with respiratory physiotherapy or olfactory rehabilitation for 12 weeks.
Category
Rehabilitation

2

Description
Intervention group: The second group will be treated with vitamin A tablets (10,000 units per day) along with the olfactory rehabilitation method for 12 weeks.
Category
Rehabilitation

3

Description
Control group: The third group of patients will not receive any treatment intervention and these patients will be followed up for 12 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghiatallah Hospital
Full name of responsible person
Abolfazl Taheri
Street address
Sheikh bahaei, Molla-Sadra Avenue, Vanak Square, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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Abolfazl Taheri
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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
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
40
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Maryam Naderi
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
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Position
Associate professor

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Specialist

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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
Undecided - It is not yet known if there will be 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
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