

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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, hypovolemia 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 hypovolemia 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)

##### Phone

+98 21 8216 2440

##### Email address

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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##### Postal code

1435915371

##### Phone

+98 21 8805 0436

##### Email

dr.abolfazl.taheri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Abolfazl Taheri

#### Street address

Sheikh bahaei, Molla-Sadra Avenue, Vanak Square, Tehran

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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

##### Street address

Sheikh bahaei, Molla-Sadra Avenue, Vanak Square, Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Abolfazl Taheri

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Bagheiat-allah University of Medical Sciences

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Maryam Naderi

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Non-faculty specialist physician

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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