Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of topical aminophylline in hyposmic and anosmic patients referred to the ENT clinic in Firoozgar hospital in 2020-2021

Protocol summary

Study aim
Determining the effect of aminophylline drops in hyposemic and anosemic patients referred to ENT clinic in Firoozgar hospital.

Design
Phase 3 randomized, parallel group trial with blinded outcome assessment of 40 patient.

Settings and conduct
In this clinical trial that was performed on 40 patients with severe hyposmia or anosmia, patients were randomized into two groups of case and placebo. In the olfactory center of the ENT department of Firoozgar hospital ,the case group was given aminophylline drops over a three-month period with olfactory training. The control group was given normal saline drops with olfactory training over a three-month period.

Participants/Inclusion and exclusion criteria
Patient with diagnosis of post viral hyposmia or anosmia, the course of olfactory dysfunction was > 6 months enter the study , and those with facial trauma, patients with nasal polyps, and those with a history of aminophylline and theophylline allergies are excluded.

Intervention groups
The case group was given aminophylline drops over three months. The control group was given normal saline drops with olfactory training over three months.

Main outcome variables
Olfactory status (hyposmia, anosmia), olfactory capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220104053625N1**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**
Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date
2022-01-10, 1400/10/20

Registrant information
Name
Pardis Rahimi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-07, 1400/11/18

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of topical aminophylline in hyposmic and anosmic patients referred to the ENT clinic in Firoozgar hospital in 2020-2021

Public title
Evaluation of the effect of topical aminophylline in hyposmic and anosmic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients older than 18 years diagnosis of post viral hyposmia or anosmia, the course of olfactory dysfunction was > 6 months signing the written informed consent to participate study
Exclusion criteria:
lack of proper compliance to the prescribed drugs history of nasal or skull base surgeries, history of nasal polyps, history of facial or nasal trauma allergies to aminophylline or theophylline consumption of other drugs.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups A and B by simple randomization method (using flip the coin method), In this way, the third person out of the study, based on the coin toss 40 times, classifies the milk patients in group A and the line in group B and is placed in a non-transparent closed envelope. Each participant is then given an envelope in order of reference. The third person throwing the coin does not know the drugs used in the groups and how the A.B. is divided. Random allocation: Deciding whether to accept or reject a company The study was first based on olfactory score and informed consent form by participants Is completed and then the participants to each The groups are randomly assigned and have no knowledge of the drugs in each group. People who work at the patient distribution center have no knowledge of our research.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participating patients did not know the contents of the drops. The third person, independent of the research team, encodes the drops containing the drug and the placebo. As a result, the person who delivers the drops and the person who collects the information have no information about the study group. The person analyzing the data also has no knowledge of the relevant coding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Rasool akram Hospital., Niayesh Ave., Sattarkhan Ave., Tehran Town

City
Tehran

Province
Tehran

Postal code
1345617615

Approval date
2020-02-04, 1398/11/15

Ethics committee reference number
IR.IUMS.FMD.REC.1398.477

Health conditions studied

1

Description of health condition studied
Patient with Post viral hyposmia

ICD-10 code
R43.0

ICD-10 code description
Anosmia

Primary outcomes

1

Description
Patients' olfactory level

Timepoint
Before the intervention and three months after taking the drops

Method of measurement
SIT (smell identification test)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aminophylline drops (using the contents of the vial aminophylline in the form of nasal drops, 250 micrograms daily) ,8 drops were used daily on each side of the nose in a head down and back position

for 3 month with olfactory training. Olfactory training was performed using four reagents with different odors, including rose, eucalyptus, lemon, and cloves. Each odorant was smelled for 10s/time, and the interval between two odorants was 10s. the training frequency was one time before breakfast and one time before sleep everyday , for 3 months.

Category

Treatment - Drugs

2

Description

Control group: given normal saline drops with olfactory training over a three-month period.8 drops were used daily on each side of the nose with olfactory training

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar hospital

Full name of responsible person
Paris Rahimi

Street address
Firoozgar hospital., Valiasr Ave., Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Vice President for Research and Technology

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Firoozgar hospital., Valiasr Ave., Tehran Town

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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Pardis Rahimi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate professor

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Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

All data can be shared

When the data will become available and for how long

Start of access period 5 months after printing the results

To whom data/document is available

Researchers working in academic institutions and science

Under which criteria data/document could be used

Research works that have a code of ethics from medical universities are allowed

From where data/document is obtainable

Firoozgar hospital., Tehran E-mail : Pardiss.rahimi@gmail.com

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

An email will be sent to the mentioned mailing address as a data requirement, it will be answered within 5 working days

Comments