Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of intranasal insulin administering on returning of the smell in patients with hyposmia.

Protocol summary

Summary

This is a randomized controlled clinical-trial double-blinded and the aim of current study is assessing therapeutic effect of intranasal insulin on hyposmic patients. Inclusion criteria: hyposmic patients with CCCRC scores 2 to 5.75; patients not are under general anesthesia in this treatment; don't use corticosteroid in treatment duration; patients aren't hypoglycemia or diabetes; patients' willingness to participate in the study. exclusion criteria: patients that cant't follow up in four months after treatment and haven't willingness to continue the study. this study will be administer on 36 hyposmic patients according to inclusion and exclusion criteria. Afterward patients will be enroll in the study. Also Patients with hyposmia should be confirm using Connecticut Chemosensory Clinical Research Center (CCCRC) criteria. Patients will randomly be divide to two groups of patients under treated with intranasal insulin or intervention group and patients under treated intranasal normal saline or placebo group. CCCRC test will be do prior to, within 12 hours, within 4, 8 and finally 16 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061712782N15**
Registration date: **2017-07-09, 1396/04/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-09, 1396/04/18

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Isfahan University of Medical Sciences .

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intranasal insulin administering on returning of the smell in patients with hyposmia.

Public title

Effect of intranasal insulin administering on patients with loss of smell

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hyposmic patients with CCCRC scores 2 to 5.75; patients not are under general anesthesia in this treatment; don't use corticosteroid in treatment duration; patients aren't hypoglycemia or diabetes; patients' willingness to participate in the study. exclusion criteria:

patients that cant't follow up in four months after treatment and haven't willingness to continue the study.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of medical sciences, Isfahan, Iran.

City
Isfahan

Postal code
7346181746

Approval date
2016-09-22, 1395/07/01

Ethics committee reference number
IR.MUI.REC.1395.30999

Health conditions studied

1

Description of health condition studied
Hyposmia

ICD-10 code
R43

ICD-10 code description
Disturbances of smell and taste

Primary outcomes

1

Description
Intensity of smell

Timepoint
before intervention and four months after intervention

Method of measurement
Connecticut Chemosensory Clinical Research Center test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients under treated with intranasal insulin

Category
Treatment - Drugs

2

Description
Control group: patients under treated with normal saline intranasal

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al Zahra Hospital

Full name of responsible person
Ahmad Rezaeian

Street address
Alzahra hospital, Alzahra street, Isfahan, Iran

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Isfahan University of Medical Sciences

Full name of responsible person
Dr Mansour Siavash

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Isfahan University of medical sciences,Hezar jarib street, Isfahan, Iran.

City
Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty