

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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Iran (Islamic Republic of)

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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 can'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

Street address

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

Contact

Name of organization / entity

Isfahan University of medical sciences, Isfahan, Iran.

Full name of responsible person

Dr Ahmad Rezaeian

Position

Otorhinolaryngologist/ Assistant professor

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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