Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of low power laser on the improvement of olfactory disorder in patients with anosmia/hyposmia

Protocol summary

Summary

The aim of this study is to determine the effects of low power laser on improving the smell of patients with post traumatic anosmia/hyposmia. This is an interventional study with control group. Statistical population includes all patients with anosmia/hyposmia due to trauma, who are referred to the Ear, Throat and Nose Research Center of Rasoule Akram Hospital. inclusion criteria including age between the ages of 20 to 45, and having post traumatic anosmia/hyposmia and exclusion criteria including congenital anomalies (Kalman Syndrome), single, having neurological diseases such as Parkinson's and Alzheimer's, Diabetes, smoking, sinonasal disease, acute nose disease such as infection and pregnancy. The sample size is 60 in the intervention group and 60 in the control group. Patients are examined by sniffin sticks two times: once at the entering to study and once two month after beginning the intervention. This test examines the odor threshold, odor discrimination and odor identification. The intervention will take 3 weeks during the study so that the intervention group during this period will be treated with a 1 watt 800 nm laser beam for three session (10 minutes once a week) and ultimately the effect of olfactory training on improvement of olfactory and sexual satisfaction will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073035386N1**
Registration date: **2017-10-10, 1396/07/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-10, 1396/07/18

Registrant information

Name

Mohamad Farhadi

Name of organization / entity

Research Center of the ear, throat, nose and head and neck of Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ear, nose and throat, and head and neck Research Center of Iran University of Medical Sciences and Health Services

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low power laser on the improvement of olfactory disorder in patients with anosmia/hyposmia

Public title

The effect of low power laser on the improvement of olfactory disorder

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age between the ages of 20 to 45; having post traumatic anosmia/hyposmia. Exclusion criteria: congenital anosmia(Kalman Syndrome); single; having neurological diseases such as Parkinson's and Alzheimer's; Diabetes; smoking; sinonasal disease; severe deviation of nasal blade; acute nasal disease such as infection; pregnancy.
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization is done using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rasoule Akram Hospital ENT research center, Iran University of Medical Sciences
Street address
2nd Floor of Building No.2, Rasoule Akram Hospital, Niayesh St., Sattarkhan Ave. Tehran
City
Tehran
Postal code
Approval date
2017-06-25, 1396/04/04
Ethics committee reference number
IR.IUMS.REC 1396.31049

Health conditions studied

1

Description of health condition studied
Post traumatic Anosmia/Hyposmia
ICD-10 code
T90-T98
ICD-10 code description
Sequelae of injuries, of poisoning and of other consequences of external causes

Primary outcomes

1

Description
Olfaction
Timepoint
at the start of study, two month after beggining of intervention
Method of measurement
Sniffin sticks tests

Secondary outcomes

empty

Intervention groups

1

Description
The control group will be left without any intervention.
Category
N/A

2

Description
The intervention group will take laser treatment for three weeks(1 session per week). These patients undergo a 10 minute session with 800 nm and 1 watts laser to repair the scar cells in the epithelial area.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoule AKram Hospital, ENT research center, Iran University of Medical Sciences
Full name of responsible person
Dr. Rafieh Alizadeh
Street address
Rasoule Akram Hospital, Niyayesh str., Satarkhan Ave, Tohid Sqr., Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Research Center of the ear, throat, nose and head and neck of Iran

Full name of responsible person

Dr. Rafie Alizadeh Miran

Street address

Niayesh str. Satarkhan str. Tohid Squ. Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Center of the ear, throat, nose and head and neck of Iran

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

Research Center of the ear, throat, nose and head and neck of Iran

Full name of responsible person

Dr. Rafie Alizadeh Miran

Position

Assistant professor/Ph.D

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Full name of responsible person

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Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

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