

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

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

Protocol summary

2017-10-10, 1396/07/18

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.

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)

Phone

+98 21 6655 2828

Email address

farhadi.f@iums.ac.ir

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

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

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 beginning 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, Niayesh 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

Street address

Niayesh str. Satarkhan str. Tohid Squ. Tehran

City

Tehran

Postal code

Phone

+98 21 64351

Fax

Email

nafiseh.alizadeh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Dr. Rafie Alizadeh Miran

Position

Assistant professor/Ph.D

Other areas of specialty/work

Street address

Niayesh str. Satarkhan str. Tohid Squ. Tehran

City

Tehran

Postal code

Phone

+98 21 64351

Fax

Email

nafiseh.alizadeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr. Rafie Alizadeh Miran

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