

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Efficacy and safety of plasma jet in periorbital rejuvenation & palpebral laxity

Protocol summary

Study aim

Efficacy and safety of plasma jet in periorbital rejuvenation in patients visiting the dermatology clinic of the Shohada-e Tajrish hospital

Design

non-blinded interventional study

Settings and conduct

A non-blinded intervention study will be carried out in Shohada-e Tajrish hospital ,for people with blepharolaxity with the aim of periorbital rejuvenation with the plasma jet and then will be evaluated with a comparison of their clinical images and the reviscometry results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with complaint of belpharolaxity
Exclusion criteria: Unwillingness to participate in the study age<35 year old History of skin infections History of neuromuscular disease uncontrolled diabetes melitus Immunsuppressant drugs pregnant or lactating females

Intervention groups

patients fulfilling the study inclusion criteria will be provided with all the information concerning the procedure and informing the research properties of the treatment. Patients will be asked to sign written consent. An expert dermatologist will evaluate all participants in this field before starting the study. After a local anesthetics cream (Lidocaine cream), the patient will be asked to wait for thirty minutes for the skin to be numbed. Before beginning the treatment, one must ensure that the skin surface is wiped clean of any local anesthetics cream. The plasma will be used first on the right eyelid and then left eyelid. These procedures will be repeated in three sessions in monthly intervals. Participants will be evaluated before treatment and one month and three months after the last treatment to evaluate the effectiveness of the treatment

Main outcome variables

Evaluation of periorbital rejuvenation Evaluation of the patient satisfaction Adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190407043192N1**

Registration date: **2019-07-23, 1398/05/01**

Registration timing: **retrospective**

Last update: **2019-07-23, 1398/05/01**

Update count: **0**

Registration date

2019-07-23, 1398/05/01

Registrant information

Name

Maryam Beheshti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 9201

Email address

ma_beheshti@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of plasma jet in periorbital rejuvenation & palpebral laxity

IR.SBMU.SRC.REC.1397.016

Public title

periorbital rejuvenation& palpebral laxity with plasma jet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with chief complaint of palpebral laxity People with 35-65 years old

Exclusion criteria:

Unwillingness to participate to the study History of skin infections such as herpes simplex History of neuromuscular or connective tissue diseases Uncontrolled diabetes melitus Immunosuppressant drugs

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Skin Research Center, Shahid Beheshti University of Medical Sciences

Street address

Skin Research Center, Shohada-e Tajrish Hospital- Shahr-dari St.-Qods Square

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Periorbital rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of periorbital rejuvenation : no response (<10%), mild response (10-25%), moderate response (25-75%), excellent response (>75%)

Timepoint

Before treatment ,one month after each treatment session , three months after the last treatment session

Method of measurement

Clinical images , Reviscometer device

Secondary outcomes

1

Description

Evaluation of the patient satisfaction

Timepoint

Before treatment, one month after each treatment session ,three months after the last treatment session

Method of measurement

Based on the patient response to the question (unsatisfactory , partial satisfaction , totally satisfied)

2

Description

Advers effects

Timepoint

Before treatment, one month after each treatment session ,three months after the last treatment session

Method of measurement

Based on the patient response to the question (infection , erythema , post inflammatory hyper or hypo pigmentation)

Intervention groups

1

Description

Intervention group: patients fulfilling the study inclusion criteria will be provided with all the information concerning the procedure and informing the research properties of the treatment. Patients will be asked to sign written consent. An expert dermatologist will evaluate all participants in this field before starting the study. After a

local anesthetics cream (Lidocaine cream), the patient will be asked to wait for thirty minutes for the skin to be numbed. Before beginning the treatment, one must ensure that the skin surface is wiped clean of any local anesthetics cream. The plasma will be used first on the right eyelid and then left eyelid. These procedures will be repeated in three sessions in monthly intervals. Participants will be evaluated before treatment and one month and three months after the last treatment to evaluate the effectiveness of the treatment.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dermatology Clinic of Shohada-e Tajrish Hospital

Full name of responsible person

Hamideh Moravvej

Street address

Shohada-e Tajrish Hospital, Shahr-dari St. Qods Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1507

Email

ma_beheshti@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Hamideh Moravvej

Street address

Shohada-e Tajrish Hospital, Shahr-dari St. Qods Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1507

Fax

+98 21 2274 4393

Email

hamidehmoravej@sbmu.ac

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Beheshti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Shohada-e Tajrish Hospital -Shahr-dari St. Qods Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1507

Email

ma_beheshti@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fahimeh Abdollahimajd

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Shohada-e Tajrish Hospital -Shahr-dari St. Qods Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1507

Email

fabdollahimajd@sbmu.ac.ir

Postal code

1989934148

Phone

+98 21 2274 1507

Email

ma_beheshti@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Beheshti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Shohadaye Tajrish Hospital-Shahrdary St. Qods Square

City

Tehran

Province

Tehran

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available