Clinical Trial Protocol
Iranian Registry of Clinical Trials
27 Sep 2021

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 blepharolaxity
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

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-Shahrdari St.-Qods Square

City
Tehran

Province
Tehran

Postal code
1989934148

Approval date
2018-12-09, 1397/09/18

Ethics committee reference number
IR.SBMU.SRC.REC.1397.016

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, Shahrdari St. Qods Square

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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

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Shohada-e Tajrish Hospital, Shahrdari St. Qods Square

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor?**
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

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Shohada-e Tajrish Hospital - Shahrdari St. Qods Square

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**Person responsible for scientific inquiries**

Contact

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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

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Shohada-e Tajrish Hospital - Shahrdari St. Qods Square

**City**
Tehran
Person responsible for updating data

Contact
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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
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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