

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of plasma spark with argon plasma and shower on face and neck skin rejuvenation

Protocol summary

Study aim

Investigating the effectiveness of using Spark plasma alone and together with other methods in reducing skin wrinkles

Design

Factorial clinical trial without control group. No blinding on 40 samples.

Settings and conduct

After examination and formation of processing groups, cases will be processed (according to the groups) at the Skin and Stem Cell Research Center of Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Exclusion criteria include the presence of active infection or history of skin cancer in the treatment area, history of keloid formation, history of hereditary or acquired connective tissue diseases, history of coagulation disorders, use of drugs involved in coagulation, having metal implants, use of "retin A" and pregnancy or breastfeeding, as well as people with skin color group V, VI, clients with artificial heart pacemakers and people under 18 years old. Also, patients who underwent cosmetic procedures around the eyes such as laser and photodynamic therapy, blepharoplasty, rhytidectomy and subcutaneous filler injections in the last 12 months were excluded from the study. Entry criteria: Having wrinkles and sagging skin

Intervention groups

The first group: the group investigating changes in skin parameters before and after processing with spark plasma The second group: the group investigating changes in the results in case of combining spark and argon The third group: the group for examining the changes in the results in case of accompanying Spark and Shaver The fourth group: the group investigating the changes in the results if spark and spray mode are combined

Main outcome variables

causing temporary inflammation and swelling in the skin

of the processed area. Creating tiny burn points in the processed area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027888N2**

Registration date: **2023-02-26, 1401/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-26, 1401/12/07**

Update count: **0**

Registration date

2023-02-26, 1401/12/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2990 4031

Email address

m_khani@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-22, 1401/12/03

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of plasma spark with argon plasma and shower on face and neck skin rejuvenation
Public title	Investigating the effect of plasma spark with argon plasma and shower on face and neck skin rejuvenation
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Having wrinkles and sagging skin in the desired areas
Exclusion criteria:	Presence of active infection history of skin cancer in the treatment area history of keloid formation history of hereditary or acquired connective tissue diseases history of coagulation disorders use of drugs involved in coagulation having metal implants use of Retin A drug pregnancy or breastfeeding people with skin color group V, VI clients with an artificial heart pacemaker patients who underwent cosmetic procedures around the eyes such as laser and photodynamic therapy, blepharoplasty, rhytidectomy and subcutaneous filler injections in the last 12 months
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	40 cases divided into 4 groups (10 processing with plasma spark, 10 processing with spark and argon jet, 10 processing with spark and shower, 10 processing with 2 different spark modes) based on the random list provided by the statistical analyst (list based on blocks randomly provided) will be processed. Placing the clients in different groups and creating a random sequence was done by Random Allocation Software 2.0 for 4 groups and 40 samples.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Factorial
Other design features	
Secondary Ids	
empty	

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Faculty of Medicine - Tehran University of Medical Sciences (Research Ethics Committee)
Street address	Laser and Plasma Research Institute, Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran
City	Tehran
Province	Tehran
Postal code	1983969411
Approval date	2023-02-19, 1401/11/30
Ethics committee reference number	IR.TUMS.MEDICINE.REC.1401.783
Health conditions studied	
1	
Description of health condition studied	Wrinkles and sagging skin
ICD-10 code	L98
ICD-10 code description	Other disorders of skin and subcutaneous tissue, not elsewhere classified
Primary outcomes	
1	
Description	Changes of collagen in the skin
Timepoint	Before starting the processes and weeks 2, 4, 6 and 10 after the processing
Method of measurement	Skin ultrasound device
2	
Description	skin elasticity
Timepoint	Before starting the processes and weeks 2, 4, 6 and 10 after the processing
Method of measurement	MPA9 multifunctional device
3	
Description	water evaporated from the skin surface
Timepoint	Before starting the processes and weeks 2, 4, 6 and 10

after the processing
Method of measurement
MPA9 multifunctional device

4

Description

Skin melanin changes

Timepoint

Before starting the processes and weeks 2, 4, 6 and 10
after the processing

Method of measurement

MPA9 multifunctional device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Processing only with dot mode of the
Plasma Spark device

Category

Treatment - Devices

2

Description

Intervention group: Processing with the dot mode of the
plasma spark device along with the argon plasma jet

Category

Treatment - Devices

3

Description

Intervention group: Processing with the dot mode of the
plasma spark device along with the plasma shower

Category

Treatment - Devices

4

Description

Intervention group: Simultaneous processing with two
point and spray mode of the spark plasma device

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No. 4, Maryam Ave, South Kamraniye

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 2267 1008

Email

nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

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City

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Province

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Postal code

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Phone

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Grant name

Grant code / Reference number

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

No

Title of funding source

Research Deputy of Tehran 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

2

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Mohammad Reza Khani

Street address

Evin, Shahid beheshti university

City

Tehran
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University
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
Laser and Plasma Research Institute/ Shahid Beheshti University
Full name of responsible person
Mohammadreza Khani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
plasma technology
Street address
Shahid Beheshti University, Daneshjo Blvd., Evin, Shahid Chamran Highway
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Person responsible for updating data

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Tehran
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available	To whom data/document is available
Analytic Code	It will be available only to researchers working in academic and scientific institutions
Yes - There is a plan to make this available	Under which criteria data/document could be used
Data Dictionary	To refer to achievements and referencing
Yes - There is a plan to make this available	From where data/document is obtainable
Title and more details about the data/document	Mohammadreza Khani +989122531497
At the end of the project, the achievements and performance of the Spark device alone and also together with other devices and methods will be published.	m_khani@sbu.ac.ir
When the data will become available and for how long	What processes are involved for a request to access data/document
The access period starts 6 months after the results are published	3 months
	Comments