

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Application of Cold Atmospheric Pressure Argon and Air Plasma to Improve the Clinical Features of the Lesions in Acne Vulgaris: Double-blind randomized clinical trial

Protocol summary

Study aim

Investigating the effectiveness of using cold argon and ambient air plasma at atmospheric pressure in healing acne vulgaris lesions

Design

The number of 24 patients in two groups (12 patients in the cold argon plasma group, 12 patients in the ambient air plasma group) based on the random list provided by the statistical analyst (the list is provided based on random blocks), undergoing eight weeks of plasma treatment. They meet once a week. G*power software was used to compare two independent samples to determine the sample size.

Settings and conduct

This research is conducted in a center (University of Tehran, Skin Stem Cell Research Center). The number of 24 patients in two groups (12 patients in the cold argon plasma group, 12 patients in the ambient air plasma group) based on the random list provided by the statistical analyst (the list is provided based on random blocks), undergoing eight weeks of plasma treatment. They meet once a week. Skin and Stem Cell Research Center, Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Entry criteria: female gender; age: 16 to 55 years old; Phototype I_ VI Fitzpatrick; the number of pores ≥ 10 in each half of the face; inflammatory lesions (papules and pustules) ≥ 50 in the whole face and ≥ 10 in each half of the face. Exclusion criteria: acne conglobata; acne fulminans; secondary acne (drugs and hormones); acne requires systemic treatment.

Intervention groups

12 patients in the cold argon plasma group, 12 patients in the ambient air plasma group

Main outcome variables

Number and clinical status of different acne lesions and the size of skin pores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027888N1**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **prospective**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

Registration date

2022-09-11, 1401/06/20

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

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Application of Cold Atmospheric Pressure Argon and Air Plasma to Improve the Clinical Features of the Lesions in Acne Vulgaris: Double-blind randomized clinical trial

Public title

Application of Cold Atmospheric Pressure Argon and Air Plasma to Improve the Clinical Features of the Lesions in Acne Vulgaris: Double-blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Phototype I_ VI Fitzpatrick The number of pores ≥ 10 in each half of the face Inflammatory lesions (papules and pustules) ≥ 50 in the whole face and ≥ 10 in each half of the face Non-inflammatory lesions (open and closed comedones) ≥ 50 in the whole face and ≥ 10 in each half of the face Maximum 4 nodules with a diameter ≥ 1 cm in the whole face Atrophic scars ≥ 50 in the whole face and of any type (needle, box, rolling) ≥ 5 in each half of the face Symmetrical distribution of lesions on both sides of the face Age 16 to 55 years old Gender: Female

Exclusion criteria:

Acne conglobata Acne fulminans Secondary acne (drugs and hormones) Nodulocystic acne Acne requires systemic treatment

Age

From **16 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The number of 24 patients in two groups (12 patients in the cold argon plasma group, 12 patients in the ambient air plasma group) based on the random list provided by the statistical analyst (the list is provided based on random blocks). Patients will be treated based on the list provided (for example, the left side of the first patient will be treated using argon plasma): 1 Left Jet 2 Right Jet 3 Left Shower 4 Right Shower 5 Left Jet 6 Right Jet 7 Left Shower 8 Right Shower 9 Left Jet 10 Right Jet 11 Left Shower 12 Right Shower 13 Left Jet 14 Right Jet 15 Left Shower 16 Right Shower 17 Left Jet 18 Right Jet 19 Left Shower 20 Right Shower 21 Left Jet 22 Right Jet 23 Left Shower 24 Right Shower How to randomize and blind

Blinding (investigator's opinion)

Double blinded

Blinding description

Clients are selected from a random list that the operator and dermatologists cannot access. In one group, for 10 minutes, half of the person's face on one side (except the

nose) is subjected to atmospheric cold plasma precipitation (shower-plasma shower-precipitation plasma), and the other is passed with the device in off mode. The patient does not know that the device is off way. In the second group, argon gas is used instead of air. Weekly visits and the duration of treatment are eight weeks. The previous design samples immediately after follow-up weeks 1, 2, 3, 4, and 8 are subjected to skin analysis and biometrics.

Placebo

Not used

Assignment

Parallel

Other design features

In order to determine the sample size for comparing two independent samples using G*power software and considering the significance level of 0.05 and the power of 0.8 and the effect size = 1.2 which is the large effect value and the ratio Assignment 1, the output of the software is as follows: Output: Sample size group 1 = 12 Sample size group 2 = 12 Total sample size = 24 Actual power = 0.8020788

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

Enghebal St. - Quds St. - Porsina St. - University North Door - Building No. 1

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1135

Health conditions studied**1****Description of health condition studied**

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Pour and their size in each visit

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

They are measured and recorded by the SKIN SCANNER device.

2

Description

Scars and their size

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

They are measured and recorded by the SKIN SCANNER device.

3

Description

Inflammatory and non-inflammatory acne lesions

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

They are measured and recorded by the SKIN SCANNER device.

4

Description

Acne severity

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

They are measured and recorded by the SKIN SCANNER device.

5

Description

Examination of skin roughness

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

They are measured and recorded by the SKIN SCANNER device.

6

Description

Skin biometric parameters

Timepoint

Variables are measured before, immediately after, one week, two weeks, three weeks, four weeks and eight weeks after the start of treatment.

Method of measurement

This item is quantitatively measured and reported by CUTOMETER and MPA 9 devices.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Argon plasma. In this method, an argon plasma device manufactured by Danesh Banyan Engineering Plasma Technology Co., Ltd. is used to process acne. In this method, the cold flame of the plasma will be shone on the acnes of one half of the face and compared with the other half of the face. This group is treated for eight weeks and one session per week.

Category

Treatment - Devices

2

Description

Second intervention group: air plasma. In this method, air plasma device manufactured by Danesh Banyan Engineering Plasma Technology Company is used to process acne. In this method, the same as the first intervention group, the process of plasma irradiation is performed.

Category

Treatment - Devices

3

Description

Control group: placebo. In this group, the other half of the face is processed by the probes of the device in the off state (the gas flow is open without electricity connection to form plasma in this group) and all the mentioned parameters are measured and recorded as in the plasma groups. .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center of Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohamad Ali Nilforoshzadeh

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
Akbar Fotouhi

Street address
Keshavarz Blvd., corner of Quds St., Central
Organization of the University, 6th floor of Research
and Technology Vice-Chancellor

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 8899 2970

Email
afotouhi@tums.ac.ir

Web page address
<http://www.tums.ac.ir/faculties/afotouhi>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

72

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
Babak Shokri

Street address
Evin Shahid beheshti university

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2990 4001

Email
b-shokri@sbu.ac.ir

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

28

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

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2990 4031

Fax
+98 21 2990 4031

Email
m_khani@sbu.ac.ir

Person responsible for scientific 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
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2990 4031
Fax
+98 21 2990 4031
Email
m_khani@sbu.ac.ir

Person responsible for updating data

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

City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2990 4031
Fax
+98 21 2990 4031
Email
m_khani@sbu.ac.ir

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

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the project, the achievements and performance of two devices on acne vulgaris will be published in a scientific article.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

To refer to achievements and referencing

From where data/document is obtainable

Mohammadreza Khani +989122531497
m_khani@sbu.ac.ir

What processes are involved for a request to access data/document

3 months

Comments