

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of Plasma Pen in the treatment of keloid scars

Protocol summary

Study aim

Evaluation of the effect of plasma device in the treatment of keloid.

Design

The non-randomized , single arm trial

Settings and conduct

Patients undergo local analgesia using lidocaine gel, we use spot by spot technique of cold plasma, the number of plasma sessions depends on the height of the Keloid.the interval between treatment sessions is one month.patients were followed up for recurrence and complication up to five months after the last treatment session.Study perform in Amir Al- Momenin teaching hospital in Tehran .

Participants/Inclusion and exclusion criteria

Inclusion criteria :patients aged 18 to 70 years with keloid scar up to 5mm in height.voluntarily and with informed consent, to be able to follow up after treatment . Exclusion criteria: people with chronic medical condition that effects wound healing and with underlying skin condition that their disease is exacerbated by skin irritation and received scar treatment in the past 6 month.

Intervention groups

People with keloids whose lesions are evaluated before and after cold plasma treatment

Main outcome variables

Improves keloid scars;Pigmentation, Vascularity, Pliability, Height of keloid, Pain, Itchiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220512054827N1**

Registration date: **2022-07-20, 1401/04/29**

Registration timing: **retrospective**

Last update: **2022-07-20, 1401/04/29**

Update count: **0**

Registration date

2022-07-20, 1401/04/29

Registrant information

Name

Sepideh Tehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

stehrani@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

2020-04-08, 1399/01/20

Actual recruitment end date

2020-09-21, 1399/06/31

Trial completion date

2021-08-11, 1400/05/20

Scientific title

Effectiveness of Plasma Pen in the treatment of keloid scars

Public title

Plasma Pen in the treatment of keloid scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 70 years old patients with keloid scars Volunteers who participated with informed consent Patients who have Possibility for repeated visits and follow-ups People

with keloid scars with a maximum height of 5mm..

Exclusion criteria:
Patients who have history of previous treatments in the last six months Patients who have any chronic medical conditions that affects wound healing. People with underlying skin condition whose disease is exacerbated by skin irritations.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **7**
Keloid scars with a diameter of about 1 mm to a maximum of 5 mm
Actual sample size reached: **24**
More than 1 sample in each individual
Actual sample size in each individual: **7**
Keloid scars with a diameter of about 1 mm to a maximum of 5 mm

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

Tehran Islamic Azad University Of Medical Sciences

Street address

Islamic Azad University of Medical Sciences, Shariati St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19395/1495

Approval date

2021-01-04, 1399/10/15

Ethics committee reference number

IR.IAU.TMU.REC.1399.369

Health conditions studied

1

Description of health condition studied

Keloid Scars

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Keloid scar improvement

Timepoint

Before treatment and 5month after end of treatment

Method of measurement

Physical examination and scoring based on the Modified Vancouver Scar Scale

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

5 months after end of treatment

Method of measurement

Answer the patient by choosing one of the option:1)not changed 2) good 3)very good 4)excellent

2

Description

Postinflammatory hyperpigmentation (PIH)as Side effects of treatment

Timepoint

10 days, one month and 5 months after the intervention

Method of measurement

Physical examination

3

Description

Recurrence

Timepoint

10 days, one month and 3 month and 5 months after the intervention

Method of measurement

Physical examination and scoring based on the Modified Vancouver Scar Scale

Intervention groups

1

Description

In each treatment session,the scar anesthetized with

lidocaine gel then the keloids are removed by spot by spot method using plasma plexr device model plus.scars with a height of 2mm and less have been treated for two session and scars with a height of more than 2mm up to 5mm have been performed for tree session. The interval between treatment session was one month.

Category

Treatment - Devices

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

Amir Al- Momenin Teaching Hospital, Islamic Azad University of Medical Sciences

Full name of responsible person

Sepideh Tehrani

Street address

Amir Al-Momenin Hospital, Shirmohammadi St., Naziabad Ave.

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

Islamic Azad University of Tehran Medical Sciences

Full name of responsible person

Sepideh Tehrani

Street address

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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

Islamic Azad University of Tehran Medical Sciences

Proportion provided by this source

100

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**

Islamic Azad University of Tehran Medical Sciences

Full name of responsible person

Sepideh Tehrani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

Islamic Azad University of Tehran Medical Sciences

Full name of responsible person

Sepideh Tehrani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shohreh delavar

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

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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

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

All study data will be shared, after unidentifiable
individuals

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

For further research

From where data/document is obtainable

Sepideh Tehrani

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

Send request by email to the responsible person

Comments