Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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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

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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
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Full name of responsible person
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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

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Person responsible for updating data

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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