

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of plasma spark with cryotherapy in Improving seborrheic keratosis in multiple patient

Protocol summary

hyperpigmentation Postinflammatory hypopigmentation atrophy scarring

Study aim

Study of a randomized clinical trial to evaluate the therapeutic effects of Spark plasma on seborrheic keratosis and compare it with cryotherapy

Design

Half of the lesions of patients with spark plasma And the other half will be done with cryotherapy by swab soaked in liquid nitrogen with two cycles of 15 seconds with the formation of a millimeter frame. Choosing the side that will be treated with plasma will be random and lucky. Patients will be evaluated at each visit after the physician assessment scale procedure, so that based on the examination, the patient's lesion will be given a score of 0 to 3. 1 = The lesion is relatively gone 2 = Residual thin lesion with a depth of one millimeter or less 3 = depth of more than one millimeter Patients will be evaluated in four visits with an interval of three weeks, ending in day 84 A statistical evaluation criterion for observing seborrheic thickness at a specific point and time is PLA scale

Settings and conduct

Half of the patients will have plasma spark lesions and the other half will receive cryotherapy

Participants/Inclusion and exclusion criteria

1-People over 18 years old 2- Has at least 4 typical and fixed seborrheic keratosis lesions 3- In logic, the lesions should not be under the pressure of the body

Intervention groups

The efficacy assessment is based on th Physician's Lesion Assessment e of the 84th day visit. Primary analysis based on the percentage of patients in each group whose 4 lesions received a zero or clear score (on day 84) Secondary analysis based on the percentage of patients in each group whose at least 3 of their 4 lesions received a zero or clear score

Main outcome variables

Gender age Number of waste seborrheic keratosis Patient skin color pla Erosion Ulcer Swelling Crust Erythema Vesicles / bullae Postinflammatory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048882N1**

Registration date: **2021-03-12, 1399/12/22**

Registration timing: **prospective**

Last update: **2021-03-12, 1399/12/22**

Update count: **0**

Registration date

2021-03-12, 1399/12/22

Registrant information

Name

Maryam Noorbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5549 3124

Email address

dr.maryamnoorbakhsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of plasma spark with cryotherapy in Improving seborrhic keratosis in multiple patient

Public title

spark in seborrhic keratosis. Effect of cryotherapy in treatment of seborrhic keratosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 years of age At least 4 lesions

Exclusion criteria:

Lesions in areas under pressure of the body

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **54**

More than 1 sample in each individual

Number of samples in each individual: **4**

clinically typical, discrete SKs that weremore than 0 to 2 mm thick and 5 to 15 mm in lengthand width.

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

9 performed as a randomization block in such a way that two people who are going to check the rat information are not aware of the randomization block, so they do not know which side of the cryo lesions and which side is sparked, but according to this The nature of the drug is different, the person performing the procedure and the patient are aware of the type of procedure performed, and this is due to the nature of the procedures used.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Thics committee of tehran University of Medical Sciences

Street address

Razi Hospital- Vahdate-e-eslami St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1199663911

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.573

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

seborrhic keratosis

ICD-10 code

L82.1

ICD-10 code description

Other seborrhic keratosis

Primary outcomes**1****Description**

PLA) scale, which is a proprietary, validated, 4-ordinal number scale (0, clear [no visibleSKs]; 1, nearly clear; 2, a thin SK 1 mm or less in depth; and, 3, a thick SK more than 1 mm in depth) developed to quantify the effect treatment of the SK

Timepoint

Four visits will be evaluated three weeks apart at the end of day 84

Method of measurement

observation of dermatologist

Secondary outcomes

empty

Intervention groups**1****Description**

The device used in this study is used using a device with the brand name "PAA Plasma Pen"; This device works in three different modes, one of which is Spark production mode. Voltage range varies between 2 to 8 kV and its frequency is 80 kHz and has a power of 0 to ten watts.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Maryam noorbakhsh sabet

Street address

Razi Hospital- Vahdate-e-eslami St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

dr.maryamnoorbakhsh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraeian

Street address

Razi Hospital- Vahdate-e-eslami St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

maryamdansh.pj@gmail.com

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

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

Tehran University of Medical Sciences

Full name of responsible person

Maryam noorbakhsh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam noorbakhsh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

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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 data is potentially shareable after unidentified individuals

When the data will become available and for how long

from 2021

To whom data/document is available

dermatologists

Under which criteria data/document could be used

Therapeutic applications of plasma spark in dermatology

From where data/document is obtainable

vahdat eslami Aven Razi hospital

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

The data will be visible for up to a week after submitting the request

Comments