

# 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

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**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

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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**

Maryam Noorbakhsh

**Position**

Resident

**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 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**