

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of efficacy and safety of electrosurgery in comparison with cryosurgery in patients with sebaceous hyperplasia, seborrheic keratosis, cherry angioma and skin tag: A controlled randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness, safety, tolerability and satisfaction of electrosurgery and cryosurgery in patients with sebaceous hyperplasia, seborrheic keratosis, cherry angioma and skin tag

Design

Clinical trial with two intervention groups, parallel, randomized, phase 2-3 on 128 patients, randomized with sealed envelopes

Settings and conduct

Each lesion is randomly assigned to one of the following two treatment groups: group a: electrosurgery and group b: cryosurgery. For lesions of the first group, electrosurgery is repeated 4 weeks later if necessary and for group b lesions, cryosurgery is repeated 2 and 4 weeks later if necessary. In order to follow up, patients in both groups, 2 weeks, 1 month and also 3 months after the initial session are visited and The data are evaluated by the patient himself, a blind dermatologist and finally the statistical specialist. Also, safety, tolerability and satisfaction of treatments are questioned in follow-up sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmation of diagnosis with a clinical examination by a dermatologist, age 18 to 70 years
Exclusion criteria: For both treatments: infection of the lesion site, history of keloid, pregnancy and lactation, malignancy, immunosuppression For electrosurgery: having an intracardiac device For cryosurgery: cold intolerance, history of Raynaud's phenomenon, vesiculobullous diseases and superficial sensory involvement

Intervention groups

group 1: Electrosurgery group 2: Cryosurgery

Main outcome variables

The rate of improvement, Lesion size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211210053344N1**

Registration date: **2021-12-28, 1400/10/07**

Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**

Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

Mojtaba Shafiei Koohpayeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6435 2390

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of electrosurgery in comparison with cryosurgery in patients with sebaceous hyperplasia, seborrheic keratosis, cherry angioma and skin tag: A controlled randomized clinical trial

Public title

Comparison of the effect of electrosurgery with cryosurgery in the treatment of sebaceous hyperplasia, seborrheic keratosis, cherry angioma and skin tag

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of diagnosis with a clinical examination by a dermatologist Age 18 to 70 years

Exclusion criteria:

Infection of the lesion site History of keloid Pregnancy and Lactation Malignancy Immunosuppression For electrosurgery: having an intracardiac device For cryosurgery: cold intolerance, history of Raynaud's phenomenon, vesiculobullous diseases and superficial sensory involvement

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

The lesions of the patients are divided into two groups using a simple randomization method, so that out of 32 sealed bags, one bag will be randomly selected for each lesion. Each envelope contains the letter a or b: a for the electrosurgery group and b for the cryosurgery group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of medical sciences

Street address

Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.IUMS.FMD.REC.1400.420

Health conditions studied

1

Description of health condition studied

sebaceous hyperplasia

ICD-10 code

L73.8

ICD-10 code description

Other specified follicular disorders

2

Description of health condition studied

seborrheic keratosis

ICD-10 code

L82

ICD-10 code description

Seborrheic keratosis

3

Description of health condition studied

cherry angioma

ICD-10 code

D18.01

ICD-10 code description

Hemangioma of skin and subcutaneous tissue

4

Description of health condition studied

skin tag

ICD-10 code

L91.8

ICD-10 code description

Other hypertrophic disorders of the skin

Primary outcomes

1

Description

Lesion size

Timepoint

At the beginning of the study, 2 weeks, 1 month and 3 months later

Method of measurement

with a ruler

2

Description

The rate of improvement

Timepoint

2 weeks, 1 month and 3 months after the beginning

Method of measurement

based on evaluation of a blind dermatologist

Secondary outcomes

1

Description

safety

Timepoint

2 weeks, 1 month and 3 months after the beginning

Method of measurement

based on side effects of the treatment (clinical evaluation)

2

Description

tolerability

Timepoint

2 weeks, 1 month and 3 months after the beginning

Method of measurement

based on Investigator Assessment of Tolerability scale

3

Description

satisfaction

Timepoint

2 weeks, 1 month and 3 months after the beginning

Method of measurement

based on Caregiver treatment satisfaction (CTS) questionnaire

Intervention groups

1

Description

Intervention group 1: For patients in this group, electrosurgery is done at the first session and repeated 4 weeks later if necessary (maximum 2 sessions). Electrosurgery is performed with biterminal monopolar electrocoagulation mode and with 20 to 40 degrees, after anesthesia with 0.2 to 0.5 cc of 2% lidocaine.

Category

Treatment - Surgery

2

Description

Intervention group 2: For patients in this group, cryosurgery is done at the first session and repeated 2 and 4 weeks later if necessary (maximum 3 sessions). Cryosurgery is performed using a spray and directly with liquid nitrogen, from a distance of 1 to 2 cm to freeze the entire lesion with a margin of 1 mm. In order to prevent

complications, two cycles of cryosurgery are performed for each lesion.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram hospital

Full name of responsible person

Afsaneh Sadeghzadeh Bazargan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Afsaneh Sadeghzadeh Bazargan
Position
Assistant professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable