

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

A comparative study of efficacy and safety of cryosurgery, electrocoagulation, CO2 laser and Erbium:YAG laser in the treatment of seborrheic keratoses

Protocol summary

Study aim

Comparison between efficacy and safety of cryosurgery versus electrocautery versus CO2 and Erbium:YAG laser in the treatment of facial seborrheic keratoses

Design

Single blind, randomized controlled clinical trial

Settings and conduct

4 similar facial seborrheic keratoses are randomly chosen and treated with one of the mentioned modalities in the Dermatology Clinic of shohada-e Tajrish Hospital. After 2 and 8 weeks, outcome assessment is done based on photographs, by 2 dermatologists who are unaware the treatment strategy used for each lesion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Age 35 to 85 2-All participants should have at least 4 seborrheic keratoses with similar size and thickness on face. Exclusion criteria: 1-History of keloid 2-History of coagulopathy or anticoagulant treatment 3-Uncontrolled diabetes 4-Uncontrolled hypertension 5-Active infection on face 6-Non-compliance with treatment and follow ups 7-History of autoimmune connective tissue disease 8-Known allergy to lidocaine or tetracaine 9-Cold intolerance 10-Cryoglobulinemia 11-Cold urticaria and any kind of cold rash

Intervention groups

Control group 1: Electrodesiccation with the same parameters on seborrheic keratosis lesions. The electrodesiccation is performed by the mode of biterminal, monopolar and with low energy. Control group 2: Cryosurgery with the same parameters on seborrheic keratosis lesions. Cryotherapy is performed with application of liquid nitrogen with an open-spray for a single 10 to 15 second freeze-thaw cycle. Intervention group 1: Er:YAG laser with the same parameters on seborrheic keratosis lesions. Intervention group 2: Co2 laser with the same parameters on seborrheic keratosis lesions.

Main outcome variables

Recovery rate of seborrheic keratosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141228020468N5**

Registration date: **2019-09-11, 1398/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-11, 1398/06/20**

Update count: **0**

Registration date

2019-09-11, 1398/06/20

Registrant information

Name

Reza Robati

Name of organization / entity

Skin Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1507

Email address

rezarobati@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of efficacy and safety of cryosurgery, electrocoagulation, CO2 laser and Erbium:YAG laser in the treatment of seborrheic keratoses

Public title

Efficacy and safety of different modalities in the treatment of seborrheic keratosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 35 to 85 All participants should have at least 4 seborrheic keratoses with similar size and thickness on face

Exclusion criteria:

History of keloid History of coagulopathy or anticoagulant treatment Uncontrolled diabetes Uncontrolled hypertension Active infection on face Non-compliance with treatment and follow ups History of autoimmune connective tissue disease Known allergy to lidocaine or tetracaine Cold intolerance Cryoglobulinemia Cold urticaria and any kind of cold rash

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

4 seborrheic keratoses with similar size and thickness on the patients face are randomly chosen and numbered from 1 to 4 and written on a set of cards ;treatment modalities are also randomly named A,B,C or D and written on another set of cards.A blinded person chooses a number from 1 to 4 from the first group and a letter from the second group representing the treatment modality.

Blinding (investigator's opinion)

Single blinded

Blinding description

In our study investigators and the assessors of the outcomes are also unaware of the study groups. 4 seborrheic keratoses with similar size and thickness on the patients face are randomly chosen and numbered from 1 to 4 and written on a set of cards ;treatment modalities are also randomly named A,B,C or D and written on another set of cards.A blinded person chooses

a number from 1 to 4 from the first group and a letter from the second group representing the treatment modality.Assessment of the final results is done by 2 dermatologists who are unaware of the treatment used for any of the lesions and is based on the photographs .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Skin Research Center, Shahid Beheshti University of Medical Sciences

Street address

Skin Research Center,Shohada-e Tajrish Hospital, Tajrish square,Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.SBMU.SRC.REC.1398.003

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

seborrheic keratosis

ICD-10 code

L82

ICD-10 code description

Seborrheic keratosis

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

The rate of recovery of seborrheic keratosis

Timepoint

Before the intervention and 2, 8 weeks after the intervention

Method of measurement

Photography before procedure and in follow up intervals, patient satisfaction

Secondary outcomes

1

Description

Pain

Timepoint

Immediately after the intervention and 2, 8 weeks after the intervention

Method of measurement

Asking the patients

2

Description

Dyspigmentation

Timepoint

Before the intervention and 2, 8 weeks after the intervention

Method of measurement

Evaluation of patients photographs by two dermatologists

3

Description

Scar

Timepoint

Before the intervention and 2, 8 weeks after the intervention

Method of measurement

Evaluation of patients photographs by two dermatologists

4

Description

Keloid formation

Timepoint

Before the intervention and 2, 8 weeks after the intervention

Method of measurement

Evaluation of patients photographs by two dermatologists

5

Description

Infection

Timepoint

2, 8 weeks after the intervention

Method of measurement

Asking the patients

Intervention groups

1

Description

Control group 1: Electrodesiccation with the same parameters on seborrheic keratosis lesions. The electrodesiccation (electrosurgical unit, MEG1, Iran Kavandish System co, made in Iran, 2013) is performed

by the mode of biterminal monopolar on seborrheic keratosis lesions with the same parameters and with low energy in one treatment session.

Category

Treatment - Devices

2

Description

Control group 2: Cryosurgery with the same parameters on seborrheic keratosis lesions. In all patients, cryotherapy is performed with the application of liquid nitrogen with an open-spray for a single 10 to a 15-second freeze-thaw cycle and in one treatment session.

Category

Treatment - Devices

3

Description

Intervention group 1: Er: YAG laser with the same parameters on seborrheic keratosis lesions. The next device used is Er: YAG laser, LOTUS II erbium device (LOTUS II; Laseroptek Co., Ltd., Sungnam, Gyenggido, Korea). We applied the energy of 500 MJ, with a spot size of 4 mm. All lesions were treated in one session and they received the same amount of energy, fluence, pulse duration, and spot size.

Category

Treatment - Devices

4

Description

Intervention group 2: Co2 laser with the same parameters on seborrheic keratosis lesions. The CO2 laser used in the study is a fractional CO2 laser (Mixel; Hironic Co., Ltd, Korea). We applied the energy of 1.5 J / cm², pulse duration of 0.4 sec and spot size of 4 mm. All lesions were treated in one session and they received the same amount of energy, fluence, pulse duration, and spot size.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e Tajrish hospital

Full name of responsible person

Dr Reza Robati

Street address

Skin Research Center, Shohada-E- Tajrish Educational Hospital, Qods Sq. , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone
+98 21 2274 1508
Email
rezarobati@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences,
Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Phone
+98 21 2243 9770
Email
Intl_office@sbm.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shirin Zaresharifi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Shahid Beheshti University of Medical Sciences,
Velenjak, Shahid Chamran Highway, Tehran, Iran

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9982
Email
shirin.zsharifi@sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Reza Robati
Position
Associate Professor of Dermatology
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Shahid Beheshti University of Medical Sciences,
Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Phone
+98 21 2274 1508
Email
rezarobati@sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shirin Zaresharifi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Shahid Beheshti University of Medical Sciences,
Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Phone

+98 21 2243 9770

Email

Shirin.zsharifi@sbmu.ac.ir

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 collected demographic data and primary and secondary outcomes are going to be shared after de-identification of the participants.

When the data will become available and for how long

These data files will become available starting 6 months after publication.

To whom data/document is available

The deidentified IPD and additional supporting information/documents will be available for people working in academic institutions.

Under which criteria data/document could be used

None

From where data/document is obtainable

To access the data files applicant can talk to Dr. Shirin Zaresharifi resident of dermatology at Shahid Beheshti University of Medical Sciences. Address: Shahid Beheshti University of Medical Sciences, Velenjak, Shahid Chamran Highway, Tehran, Iran Postal code: 1985717443 Email address:shirin.zsharifi@sbmu.ac.ir Phone number: 0098 21 2243 9982 Mobile number: 0098 912 846 5784

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

The applicants should follow Shahid Beheshti University of Medical Sciences process and protocols for accessing the data files.

Comments