

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of seborrheic keratosis lesions: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of seborrheic keratosis lesions

Design

This is a Phase III single-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the Sina Hospital in Hamadan city, involving 40 eligible patients with seborrheic keratosis lesions. The right and left sides of the patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Bilateral facial seborrheic keratosis Exclusion criteria: Pregnancy or breastfeeding History of using anti-pigmentation drugs in the last 3 months Presence of wound, infection or active skin disease at the treatment site Lesions on the eyelids or around the eyes

Intervention groups

Intervention group: In the hydrogen peroxide treatment method, a 40% hydrogen peroxide solution is placed on the seborrheic keratosis lesions with a cotton swab for 20 seconds and repeated after 60 seconds. This treatment is repeated once a week for 6 weeks. Control group: In the cryotherapy treatment method, a cotton swab dipped in liquid nitrogen is placed on the seborrheic keratosis lesions with a margin of 1 to 2 mm from the surrounding healthy skin until it is frozen and after complete melting, this operation is repeated again. This treatment is repeated every two weeks for 6 weeks.

Main outcome variables

Primary outcome: Improvement rate of keratosis

seborrheic lesions Secondary outcome: Pain, Erythema, Edema, Hypopigmentation, Hyperpigmentation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N489**

Registration date: **2023-11-09, 1402/08/18**

Registration timing: **prospective**

Last update: **2023-11-09, 1402/08/18**

Update count: **0**

Registration date

2023-11-09, 1402/08/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of seborrheic keratosis lesions: a single-blind randomized clinical trial

Public title
Effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of seborrheic keratosis lesions

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 70 years Bilateral facial seborrheic keratosis
Exclusion criteria:
Pregnancy or breastfeeding History of using anti-pigmentation drugs in the last 3 months Presence of wound, infection or active skin disease at the treatment site Lesions on the eyelids or around the eyes

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

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of the right and left sides of the patients to the intervention and control groups will be carried out using the drawing of lots. To achieve this, two sheets will be prepared, one with "right" written on it and the other with "left." For each patient, one sheet will be randomly taken from the container. Based on whether the given sheet is labeled as "right" or "left," it will be assigned to the intervention group or the opposite side will be allocated to the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a single-blind study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-10-28, 1402/08/06

Ethics committee reference number

IR.UMSHA.REC.1402.490

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

Improvement rate of keratosis seborrheic lesions

Timepoint

In 2, 4, and 6 weeks after treatment

Method of measurement

By clinical examination

Secondary outcomes

1

Description

Pain and burning

Timepoint

20 minutes after treatment

Method of measurement

By taking history

2

Description

Erythema

Timepoint

20 minutes after treatment

Method of measurement

With clinical examination

3

Description

Edema

Timepoint

20 minutes after treatment

Method of measurement

With clinical examination

4

Description

Hypopigmentation

Timepoint

20 minutes after treatment

Method of measurement

With clinical examination

5

Description

Hyperpigmentation

Timepoint

20 minutes after treatment

Method of measurement

With clinical examination

Intervention groups

1

Description

Intervention group: In the hydrogen peroxide treatment method, a 40% hydrogen peroxide solution is placed on the seborrheic keratosis lesions with a cotton swab for 20 seconds and repeated after 60 seconds. This treatment is repeated once a week for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: In the cryotherapy treatment method, a cotton swab dipped in liquid nitrogen is placed on the seborrheic keratosis lesions with a margin of 1 to 2 mm from the surrounding healthy skin until it is frozen and after complete melting, this operation is repeated again. This treatment is repeated every two weeks for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Forough Bouryabaf

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

foroughbouryabaf@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Forough Bouryabaf

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

foroughbouryabaf@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Bahareh Ebrahimi

Position

Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

b.ebrahimi.4362@googlel.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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

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