# 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)

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**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**

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**Postal code**

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**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**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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