Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of therapeutic, immunity and efficacy of topical hydrogen peroxide solution (40% vol) with cryotherapy in seborheic keratosis.

Protocol summary

Study aim
Comparison of therapeutic, safety and efficacy effects of topical hydrogen peroxide solution (40% by volume) with cryotherapy in Seborrheic keratosis lesions

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. Patients will be randomly divided into intervention and control groups using the outpatient file number and the random number table.

Settings and conduct
Sina Hospital, Tabriz, Admission of 90 patients to the study based on inclusion and exclusion criteria and classification into intervention and control groups, double-blind study, classification of patients into groups A and B, patients،lack of information about type of treatment among patients and data analyzer.

Participants/Inclusion and exclusion criteria
1)Age over 18 years 2) Seborrheic keratosis with definitive diagnosis based on diagnostic criteria: (presence of at least one separate lesion on the face and a separate lesion on trunk or limbs with a depth of 0 to 2 mm and a length and width of 5 to 15 mm) 3)Presence of at least 4 seborrheic keratosis lesions in patient 4) Acceptance to participate in the study

Intervention groups
Patients with seborrheic keratosis treated with topical hydrogen peroxide solution

Main outcome variables
Physician’s Lesion Assessment Scale) PLA(, seborrheic keratosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220117053747N2**
Registration date: **2022-03-25, 1401/01/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-25, 1401/01/05**
Update count: **0**

Registration date
2022-03-25, 1401/01/05

Registrant information

Name
Armaghan Ghareh aghaji zare

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-22, 1400/11/02

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of therapeutic, immunity and efficacy of topical hydrogen peroxide solution (40% vol) with cryotherapy in seborheic keratosis.

Public title
Comparison of therapeutic, immunity and efficacy of topical hydrogen peroxide solution (40% vol) with

cryotherapy in seborheic keratosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Patient with definite diagnosis of seborrheic keratosis according to diagnostic criteria (Existence of at least one separate lesion in the trunk or limbs with a depth of 0 to 2 mm and length and width of 5 to 15 mm) Existence of at least 4 lesions of seborrheic keratosis in the individual Satisfaction to participate in the study

Exclusion criteria:

Presence of the lesion at the site of hair growth (so that the medicine does not reach the lesion well) Presence of a lesion on the eyelid Lesions at a distance of 5 mm from the eye

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to an outpatient file number and a table of random numbers to two intervention and control groups will be divided. Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and has become a table. In order to use random numbers, first determine the table to read the numbers, from left to right, the second assumption is to consider numbers for different groups, even numbers for the intervention group and odd numbers for Control group

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are divided into two groups A and B and the data analyzer is not aware of the treatment received by each group. Blinding is used to reduce the error rate. In this study, double-masked blinding is used in which both patients and evaluators of patient-related data are unaware of the exposure received. In these studies, the groups are identified by a code A and B, which is placed in an envelope, and elsewhere, it is specified that this group number is an intervention or a control.

Placebo

Not used

Assignment

Parallel

Other design features

Data collection method: The data obtained will be recorded by a data collection form designed by the researcher. Data analysis method: The data obtained by SPSS statistical analysis software version 21 will be statistically analyzed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

No. 3, 3rd Floor, East Avang Alley, Parvin Etesami St., Fatemi St., Tehran

City

Tabriz

Province

East Azarbaijan

Postal code

1413845446

Approval date

2020-12-28, 1399/10/08

Ethics committee reference number

IR.TBZMED.REC.1399.914

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 effectiveness of the treatment will be assessed by the Physician's Lesion Assessment Scale (PLA). The scoring of this scale is 4 numbers (0 = no lesion; 1 = almost no lesion; = Lesions with a depth of more than 1 mm) Patients will be evaluated by this scale at the time of the first visit, 3 weeks later, 6 weeks later and 8 weeks after receiving the treatment. will be.

Timepoint

Physician’s lesion assesment scale measurement at the time of the first visit, 3 weeks later, 6 weeks later and 8 weeks after receiving treatment

Method of measurement

Physician’s lesion assesment scale score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive topical hydrogen peroxide solution (40% by volume). The solution will be applied to the lesion so that it covers the entire surface of the lesion and then held for 20 seconds with rotational movements and pressure on the lesion. This operation is performed for all 4 lesions and the drug will be applied in each session for a total of 80 seconds. This cycle will be repeated 4 times in each session, which will be a total of 320 seconds. Patients will be monitored for pharmacological and dermatological side effects for at least 20 minutes after application of the solution. The effects of treatment, efficacy and safety of medication will be evaluated and in the next 8 weeks visit, patients will be evaluated only for the effects of treatment, efficacy and safety of medication and will not receive intervention.

Category

Treatment - Drugs

2

Description

Control group: Cryotherapy for the control group performed at the first visit, 3 weeks later and 6 weeks later And each time patients will be evaluated for the effects of treatment, efficacy and safety of medication and at the visit 8 weeks later Patients will only be evaluated for the effects of treatment, efficacy and safety of medication and will not receive intervention

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Hossein Garavand

Street address
Tabriz, Azadi St., between Shahid Montazeri and Hafez intersections, Sina Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Mohammad Samiee

Street address
thired floor, central billing number two, Golgasht street

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5138665793

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Samiei.moh@Gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Armaghan Gharehaghajizare

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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
No - There is not 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
study data is categorized and coded with no identifiable individuals.
When the data will become available and for how long
access to study data after publication of the results is available in the journal
To whom data/document is available
anyone interested in using the data can access the study data.
Under which criteria data/document could be used
study data can be used for comparison with other results.
From where data/document is obtainable
refer to the study’s scientific or public accountability person for data.
What processes are involved for a request to access data/document
the request will be sent by email to person responsible for scientific or public inquiries.
Comments