Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of treatment of actinic keratosis with 35% hydrogen peroxide in comparison to cryotherapy

Protocol summary

Study aim

Evaluation of therapeutic effects on dermoscopic manifestations & complications of hydrogen peroxide on actinic keratosis and its comparison with cryotherapy in patients admitted to Razi Hospital in 2018; We also examined the effect of age and history of radiotherapy and skin color on this study

Design

A randomized clinical trial with control group

Settings and conduct

group of 25 patients is selected. Each patient's side of the drug application is selected by Block Randomization. Treatment of these patients is performed by the physician in the first session and is repeated on days 22 & if there is Failure to heal one more session after 3 weeks. Clinical examinations, photography and dermoscopy are performed at each visit. Finally, two dermatologists were blindly reviewing the photos

Participants/Inclusion and exclusion criteria

A group of 25 patients from patients who are referred to the dermatology clinics of Razi Hospital who had at least 4 actinic keratosis on sun exposed areas and who had not received any other treatment for these lesions are going to be selected.

Intervention groups

In each treatment session, the lesion is completely cleansed with isopropyl alcohol and then the drug used on one side of the scalp with a single-use applicator rotated firmly for approximately 20 seconds on the lesions & again after 60 minutes the procedure will be repeated for three other rounds. To perform cryotherapy on the lesion control side, liquid nitrogen on one side of the scalp with a disposable applicator rotating at a pressure of approximately 15 seconds & again after 60 minutes the procedure will be repeated for one other round. to the extent that a 1–2 mm margin is created around the scrape.

Main outcome variables

Replacement of hydrogen peroxide solution with cryotherapy in the treatment of AK with similar or greater efficacy and fewer complications and greater ease of use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044912N1**
Registration date: **2021-04-23, 1400/02/03**
Registration timing: **retrospective**

Last update: **2021-04-23, 1400/02/03**
Update count: **0**

Registration date

2021-04-23, 1400/02/03

Registrant information

Name

Delara Amir Dastmalchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2241 8337

Email address

delara.adastmalchi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of treatment of actinic keratosis with 35% hydrogen peroxide in comparison to cryotherapy

Public title

Evaluation of treatment of actinic keratosis with hydrogen peroxide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are at least 18 years old with at least 4 actinic keratosis on the skin areas that are sun exposed

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient's side drugs application is selected by using Block Randomization & Finally, two dermatologists will blindly examine the dermographic and dermoscopic photographs and determine the extent of lesion healing based on the dermoscopic manifestations.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, two dermatologists will blindly examine dermographic and dermoscopic photographs and compare the therapeutic effects and side effects of these two methods, as well as Each patient's side for drug's application is selected by using Block Randomization

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Razi Hospital, Vahdat-e-Eslami Square, Vahdat-e-Eslami Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

۱۱۹۹۶۶۳۹۱۱

Approval date

2019-06-22, 1398/04/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.239

Health conditions studied

1

Description of health condition studied

actinic keratosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of recovery

Timepoint

day 21 - day 42 - day 63 - day 96

Method of measurement

Examines the dermographic and dermoscopic photos taken with the FotoFinder device

2

Description

complications

Timepoint

day 21 - day 42 - day 63 - day 96

Method of measurement

Examines the dermographic and dermoscopic photos taken with the FotoFinder device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hydrogen peroxide 35%,in each session: 20 secconds of application for 4 times, at least 3 session with 21 days interval

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Delara Amir Dastmalchi

Street address
razi hospital, Vahdat Eslami Square, Tehran, Iran.

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Email
razihospital@sina.tums.ac.ir

Web page address
http://razihos.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
ali sadeghi nia

Street address
Razi hospital, Vahdat Eslami Square, Tehran, Iran.

City
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http://razihos.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
ali sadeghi nia

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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