Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of clinical and dermoscopic effects of topical use of KOH 5% solution on Actinic Keratosis and its comparison with 5-Fluorouracil topical cream on patients suffering Actinic Keratosis.

Protocol summary

Study aim

Specifying the therapeutic effects of KOH 5% in comparison to 5-Fluorouracil cream on Actinic Keratosis (main aim). Specifying the relationship between the therapeutic effects of KOH 5% and 5-Fluorouracil cream with patient's age, radiotherapy histor, and patient's skin color classification based on Fitzpatrick scale (secondary aims).

Design

KOH 5% is used on half of the lesions and 5-Fluorouracil cream is used on the other half. Sides on which, each drug is used for each patient, is randomized using four-way Block Randomization method. Lesions are divided into 2 groups of left side lesions (L) and right side lesions (R). The fact that each number (patient) uses which drug on which side, is randomized. The sample size is 25 people.

Settings and conduct

Patients suffering Actinic Keratosis attending Razi dermatology hospital will be using both medicines simultaneously for 4 weeks. All patients will be examined before the intervention begins, 14, 28, 60 and 90 days after starting treatments. The clinical traits of the lesions and their improvement process will be examined and photographed using "FotoFinder" dermoscope and will then be analyzed by two of the dermatology professors who will have a blind observation on the taken pictures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Actinic Keratosis patients who are at least 18 years old, and have a minimum number of 8 lesions (at least 4 per side) on parts of skin exposed to the sun. Exclusion criteria: All pregnant women and people with a history of allergy to any of the drugs under study.

Intervention groups

Checking the therapeutic effects of KOH 5% on half of a person's lesions of Actinic Keratosis (As intervention group) in comparison to the effects and side effects of 5-Fluorouracil cream on the other half of lesions (As control group).

Main outcome variables

Smoothing of Actinic Keratosis's roughness of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040978N1**
Registration date: **2018-10-19, 1397/07/27**
Registration timing: **prospective**

Last update: **2018-10-19, 1397/07/27**
Update count: **0**

Registration date

2018-10-19, 1397/07/27

Registrant information

Name
Ali Salehi Farid
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of clinical and dermoscopic effects of topical use of KOH 5% solution on Actinic Keratosis and its comparison with 5-Fluorouracil topical cream on patients suffering Actinic Keratosis.

Public title
Evaluation of treatment of actinic keratosis with KOH5% solution in comparison to Fluorouracil 5% cream
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients suffering Actinic Keratosis attending Razi dermotology hospital Having at least 18 years of age Having a minimum number of 8 lesions(4 on each side, at least) on parts of skin that are exposed to the sun.
Exclusion criteria:
Pregnant women People with a history of allergy to any of the drugs under study.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **8**
Having a minimum number of 8 lesions(4 on each side, at least) on parts of skin that are exposed to the sun.
Randomization (investigator's opinion)
Randomized
Randomization description
Sides on which, each drug is used for each patient, is randomized using four-way Block Randomization method. Patients are numbered 1 to 25. Lesions are divided into two groups of left side lesions (marked with letter L) and right side lesions (marked with letter R). The fact that each number (patient) uses which drug on which side (left side lesions (L) or right side lesions (R)), is randomized using Block Randomization method. In fact, each patient's lesions are considered the statistical society, so randomization has taken place within each individual.
Blinding (investigator's opinion)
Not blinded
Blinding description
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
13th F̈lr., Block A, Central HQ̈s of the Ministry of Health & Medical Education, Simaye_Iran St., Qods Town
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2018-06-20, 1397/03/30
Ethics committee reference number
IR.TUMS.TIPS.REC.1397.010

Health conditions studied

1

Description of health condition studied
Actinic Keratosis
ICD-10 code
L57.0
ICD-10 code description
Actinic keratosis

Primary outcomes

1

Description
Smoothing of Actinic Keratosis's lesions' roughness
Timepoint
At the beginning of the study (Before the intervention begins) and 14, 28, 60 and 90 days after starting the use of KOH 5% solution and Fluorouracil cream
Method of measurement
Clinical diagnosis by dermatologist

Secondary outcomes

1

Description
The improvement of dermoscopic features of Pseudo-network pattern's lesions.
Timepoint

At the beginning of the study (before the intervention begins) and 14, 28, 60 and 90 days after starting the treatment using KOH 5% solution and Fluorouracil cream

Method of measurement

Analyzing the photographed dermoscopic discoveries using a FotoFinder by two dermatology professors.

2

Description

The improvement of dermoscopic feature of Yellow scales' lesions.

Timepoint

At the beginning of the study (before the intervention begins) and 14, 28, 60 and 90 days after starting the treatment using KOH 5% solution and Fluorouracil cream

Method of measurement

Analyzing the photographed dermoscopic discoveries using a FotoFinder by two dermatology professors.

3

Description

The improvement of dermoscopic feature of White scales' lesions.

Timepoint

At the beginning of the study (before the intervention begins) and 14, 28, 60 and 90 days after starting the treatment using KOH 5% solution and Fluorouracil cream

Method of measurement

Analyzing the photographed dermoscopic discoveries using a FotoFinder by two dermatology professors.

4

Description

The improvement of dermoscopic feature of Linear-Wavy Vessels' lesions.

Timepoint

At the beginning of the study (before the intervention begins) and 14, 28, 60 and 90 days after starting the treatment using KOH 5% solution and Fluorouracil cream

Method of measurement

Analyzing the photographed dermoscopic discoveries using a FotoFinder by two dermatology professors.

5

Description

The improvement of dermoscopic feature of Pigmented Dots' lesions

Timepoint

At the beginning of the study (before the intervention begins) and 14, 28, 60 and 90 days after starting the treatment using KOH 5% solution and Fluorouracil cream

Method of measurement

Analyzing the photographed dermoscopic discoveries using a FotoFinder by two dermatology professors.

Intervention groups

1

Description

Intervention group: Patients suffering Actinic Keratosis attending Razi dermatology hospital who are at least 18 years old and have a minimum number of 8 lesions (4 on each side, at least) on parts of skin that are exposed to the sun, will be recognized. A group of 25 people is chosen from among these patients. The chosen patients are explained about the medicine, the manner of using the medicine, probable side effects, mandatory use of sun screen and the importance of signing the letter of satisfaction. KOH 5% (Produced and packed in Razi hospital's laboratory of compounding drugs) and Fluorouracil 5% cream (This medicine is available in pharmacies under commercial name of Efudix in 20-gram tubes) are handed to the patients. Patients will be using the two medicines simultaneously for 4 weeks. Patients are taught to use KOH 5% for one half of the lesions and Fluorouracil 5% cream for the other half.

Category

Treatment - Drugs

2

Description

Control group: Patients suffering Actinic Keratosis attending Razi dermatology hospital who are at least 18 years old and have a minimum number of 8 lesions (4 on each side, at least) on parts of skin that are exposed to the sun, will be recognized. A group of 25 people is chosen from among these patients. The chosen patients are explained about the medicine, the manner of using the medicine, probable side effects, mandatory use of sun screen and the importance of signing the letter of satisfaction. KOH 5% (Produced and packed in Razi hospital's laboratory of compounding drugs) and Fluorouracil 5% cream (This medicine is available in pharmacies under commercial name of Efudix in 20-gram tubes) are handed to the patients. Patients will be using the two medicines simultaneously for 4 weeks. Patients are taught to use KOH 5% for one half of the lesions and Fluorouracil 5% cream for the other half.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Hamidreza Mahmoudi

Street address

Razi Dermatology Hospital, Razi Dead-end, Vahdat Eslami Sq., Vahdat Eslami St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology

Street address
6th Flr., Vice Chancellor for Research and Technology, Central Organization of University, Qods St., Keshavarz Blvd.

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1417653761

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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
Hamidreza Mahmoudi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali Salehi Farid

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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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

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 data are shareable, except for patients' pictures, after anonymizing the patients.

When the data will become available and for how long

All data are shareable 6 months after publishing the results, except for the patients' pictures, after anonymizing the patients.

To whom data/document is available

Researchers working in universities or science institutions or people working in industrial areas, can receive the data or other documents on the study.

Under which criteria data/document could be used

The data or the other documents on the research, except for patients' pictures, can be used for systematic review or any other purpose provided having legal permission from the owners of the study.

From where data/document is obtainable

1: Dr. Hamidreza Mahmoudi E-mail address: hr_mahmoody@yahoo.com Mobile-phone number: 00989122612946 Razi hospital 2: Dr. Ali Salehi Farid E-mail address: ali.salehi.farid@gmail.com Mobile-phone number: 00989123711774

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

Using the data or documents is possible after one month, provided having the legal permission of the owners of the study, by one of the authorized people.

Comments