Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Clinical trial of Comparison of the efficacy of two topical drugs fluorouracil 5% and niacin amide 1% in the treatment of patients with actinic keratosis

Protocol summary

Study aim

1. Finding appropriate and uncomplicated treatment in patients with actinic keratosis 2. Comparison of the efficacy of fluorouracil and niacinamid for treatment of frontal fibrosing alopecia

Design

A clinical trial with parallel, randomized, phase 2 groups was performed on 88 lesion patients.

Settings and conduct

Samples will be selected from patients referred to Isfahan University of Medical Sciences.Patients are randomly divided into two treatment groups if they meet the inclusion criteria.Actinic keratosis lesions are imaged and dermoscopic grading is determined.In each group, 44 actinic keratosis lesions are included.Patients are divided into two groups: fluorouracil and niacinamide.In the fluorouracil group, patients treated with 5% fluorouracil topical cream twice daily for 4 weeks and in the niacinamide group, patients treated with 1% niacinamide topical gel twice daily for 12 weeks.In the fluorouracil group, patients are evaluated at 2 and 8 weeks, and in the niacinamide group, patients are evaluated at 8 and 12 weeks.The degree of improvement and n dermoscopic grading and treatment complications are evaluated.

Participants/Inclusion and exclusion criteria

entry conditions :New patients with actinic keratosis who have not received any medication so far; Patients who have previously received topical medication and have not received topical medication for at least one month; People 18 years of age and older; Non-hyperkeratotic lesions.non entry conditions:Using other local treatments at the site of lesions

Intervention groups

1- A group of patients with 44 lesions are treated with topical fluorouracil once a day for 1 month. 2- A group of patients with 44 lesions are treated with topical niacinamid twice a day for 3 months.

Main outcome variables

1. Dermoscopic grading 2. improvement rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220519054920N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**
Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Mahbube Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 5414

Email address

mah.brti@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-06-19, 1402/03/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of Comparison of the efficacy of two topical drugs fluorouracil 5% and niacin amide 1% in the treatment of patients with actinic keratosis

Public title
The effect of two topical drugs fluorouracil 5% and niacin amide 1% in the treatment of patients with actinic keratosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New patients with actinic keratosis who have not yet received any medication Patients who have previously received topical medication and have not received topical medication in at least one month People aged 18 and over Non-hyperkeratotic lesions
Exclusion criteria:
Existence of other skin diseases at the treatment site History of hypersensitivity to fluorouracil or niacin acid Pregnant and lactating women
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **88**
More than 1 sample in each individual
Number of samples in each individual: **3**
Actinic keratosis
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is performed among patients referred to dermoscopy clinic affiliated to the esfahan university of medical science and if they have the conditions to enter and leave the study are considered as an sample. Random function of Excel software based on patient file number will be used for randomization. Patients with actinic keratois are entered in Excel according to the file number and are divided into two groups of fluorouracil and niacinamide based on the random button.
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 Esfahan University of Medical Sciences
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran
City
esfahan
Province
Isfehan
Postal code
8174755636
Approval date
2021-09-04, 1400/06/13
Ethics committee reference number
IR.MUI.MED.REC.1400.445

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
improvment rate
Timepoint
Before and after intervention
Method of measurement
Scoring based on the opinion of two dermatologists

2

Description
Dermoscopic grading
Timepoint
Before and after intervention
Method of measurement
Based on scoring by two dermatologist

3

Description
Complications of treatment
Timepoint

Weeks 4 and 8 in the fluorouracil group and weeks 6 and 12 in the niacinamid group

Method of measurement

Asking the patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:In the first group, 44 lesions are entered. First, the lesions of each patient are determined precisely by examination and using dermoscopy, then the lesions are photographed and 5% fluorouracil topical cream is prescribed for the patients. Patients use the medicine topically once a day and during a period of 4 weeks at the designated lesion site.The manufacturer of 5% fluorouracil cream is "Meda" company of Sweden.

Category

Treatment - Drugs

2

Description

Intervention group2 :In the second group, 44 lesions are included. First, each patient's lesions are determined precisely by examination and using dermoscopy, then the lesions are photographed and 1% niacinamide topical gel is prescribed for the patients. Patients use the drug twice a day for a period of 3 months at the site of the determined lesions.Niacinamide 1% topical gel is produced by a pharmacist in the form of niacinamide powder in the gel base.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mahbube Barati

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Alzahra Hospital, Dermatology Department, Sofeh Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh hagh joo javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahbube Barati

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mahbube Barati

Position
Dermatology resident

Latest degree
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Latest degree
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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
Dissemination of data that has nothing to do with the personality and identity of the participants in the study and are merely the consequences of the study.

When the data will become available and for how long
Start the access period after the article is published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions, after their authentication by the relevant university.

Under which criteria data/document could be used
The data can only be used for research and writing review articles.

From where data/document is obtainable
The author will be available via the email and university phone number mentioned in the article.

What processes are involved for a request to access data/document
Access to the data is granted if it is found that the data has been requested for non-industrial and non-commercial use.

Comments