

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comparative study of the effect of nanofibers containing 5% 5-Fluorouracil and rosemary extract and nanofibers containing 5% 5-Fluorouracil and 5% 5-Fluorouracil cream on Actinic Keratosis Lesions Treatment

Protocol summary

Study aim

The main goal of this study is to compare the effectiveness of nanofibers and creams containing 5% 5-fluorouracil in the treatment of Actinic keratosis. Also, the effect of Rosemary extract on the treatment is identified.

Design

parallel-group randomized controlled blinded phase 2 trial with 15 patients and 45 lesions

Settings and conduct

A non-blinded dermatologist evaluates the patients in Sedighe Tahere hospital before treatment, reaching the clinical diagnosis of actinic keratosis. The dermatologist determines lesions and records the primary photographic images. The treatment period takes 4 weeks. The same dermatologist evaluates the patients 2 weeks after treatment and verifies the presence of adverse effects. The dermatologist also records the new photographic images and evaluates the improvement of the lesions. Then, a blinded dermatologist evaluates the photographs and rates the improvement of the lesions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of actinic keratosis, At least 18 years old, Willing to participate in the study
Exclusion criteria: Previous history of allergy to formulation ingredients, patients with lip lesions, pregnant and breastfeeding mothers, taking immunosuppressive drugs, cytotoxic drugs, and/or systemic corticosteroids, Use of any drugs for the treatment of lesions over the 4 passed weeks

Intervention groups

Control group: Patients take 5% 5-fluorouracil cream. They take the cream every night for 4 weeks.
Intervention group 1: Patients take the nanofibers containing 5% 5-fluorouracil. They take nanofibers every night for 4 weeks. Intervention group 2: Patients take the

nanofibers containing 5% 5-fluorouracil and 5% standardized Rosemary extract. They take nanofibers every night for 4 weeks.

Main outcome variables

The investigator global improvement score

General information

Reason for update

Because of the lack of primary predicted time for recruitment and conditions caused by Coronavirus that occurred to the reduction of patient visits, we should increase the recruitment time and decrease the sample size.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050067N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-07-09, 1400/04/18**

Update count: **1**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Erfaneh Ghassami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study of the effect of nanofibers containing 5% 5-Fluorouracil and rosemary extract and nanofibers containing 5% 5-Fluorouracil and 5% 5-Fluorouracil cream on Actinic Keratosis Lesions Treatment

Public title

effect of 5-fu and rosemary extract polymeric wound dressing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of actinic keratosis at least 18 years old consent of the individual to participate in the study

Exclusion criteria:

Previous history of allergy to formulation ingredients pregnant or lactating mothers patients on immunosuppressive, immunomodulatory, cytotoxic, and systemic steroid drugs patients who received treatment for their lesions in the 4 weeks preceding the study patients with lip lesions (because of prevention of changing into Squamous cell carcinoma)

Age

From 18 years old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 15

More than 1 sample in each individual

Number of samples in each individual: 3

At least 3 Actinic Keratosis lesions

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with the table of random number

Blinding (investigator's opinion)

Single blinded

Blinding description

A non-blinded dermatologist (investigator) evaluates the patients before treatment, reaching the clinical diagnosis of actinic keratosis. The dermatologist determines

lesions and their location through the photographic image. The same dermatologist evaluates the patients 2 weeks after treatment and verify the presence of adverse effects. The dermatologist also records new photographic images (under the same conditions of light and distance that the first ones were taken) evaluating the improvement of the lesions according to the Investigator Global Improvement Score and the patient's degree of satisfaction through the visual analog scale Score. A blinded dermatologist evaluate the photographs and rate the improvement of the lesions through the Investigator Global Improvement Score.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق در پژوهش معاونت تحقیقات و فناوری-دانشگاه علوم پزشکی اصفهان

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Approval date

2020-12-09, 1399/09/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.619

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

Treatment of cutaneous lesions

Timepoint

at the beginning and after 6 weeks

Method of measurement
Global improvement score

2

Description
Patient satisfaction

Timepoint
6 weeks after starting the use of nanofibers and Fluorouracil cream

Method of measurement
Visual Analogue Scale Score

Secondary outcomes

1

Description
Adverse effects

Timepoint
6 weeks after starting the use of nanofibers and Fluorouracil cream

Method of measurement
Ask the patient and Physical examination

Intervention groups

1

Description
Control group: Patients take 5% 5-fluorouracil cream from Meda Co. They take the cream every night until the next morning for 4 weeks.

Category
Treatment - Drugs

2

Description
Intervention group: Patients take the Polyvinyl alcohol nanofibers containing 5% 5-fluorouracil. They take nanofibers every night until the next morning for 4 weeks.

Category
Treatment - Drugs

3

Description
Intervention group: Patients take the Polyvinyl alcohol nanofibers containing 5% 5-fluorouracil and 5% standardized Rosemary extract. They take nanofibers every night until the next morning for 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Sedighe Tahereh hospital

Full name of responsible person
Zabihollah Shahmoradi

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Khorram St., jomhouri-e-Eslami sq., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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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

Nazila Poostiyan

Position

Assistant Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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

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Student

Latest degree

Medical doctor

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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