Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 31 3792 7118

Email address

e.ghassami@pharm.mui.ac.ir

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
Street address
Hezar Jerib St., Medical University of Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
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
Street address
Khorram St., jomhouri-e-Eslami sq., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3335 9933
Fax
+98 31 3337 3733
Email
emrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
Street address
Hezar Jerib st., Medical University of Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3071
Email
isrc@mui.ac.ir
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
Street address
Al-Zahra Hospital, Soffeh Blvd., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
n.poostiyan@med.mui.ac.ir

Person responsible for scientific 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
Street address
Al-Zahra Hospital, Soffeh Blvd., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
n.poostiyan@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Reza Jamali
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid ghadiri ally., Motahari Blvd,. Kashan
City
Kashan
Province
Isfehan
Postal code
8174884841
Phone
+98 31 5554 3055
Email
reza_jamali1996@yahoo.com

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