Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of topical adjuvant treatment of psoriasis with recombinant Epidermal Growth Factor to control the e-regulation of the Epidermal Growth Factor Receptor (EGFR): clinical trial phase 2

Protocol summary

Study aim

Evaluation of topical cream containing recombinant epidermal growth factor on patients with psoriasis

Design

21 patients with two active plaque in the second phase of the clinical trial will be randomly assigned. To avoid disparity between group sizes, we will use replacement randomization until we achieve a balanced group size. The intervention area will receive a cream containing recombinant epidermal growth factor and the control group will receive cream without growth factor. The evaluation will be continued twice a day for a month.

Settings and conduct

The study will be performed at the skin and stem cell research center, Tehran University of Medical Sciences. In this study, participants and data collectors will be blind to the type of topical cream.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Informed consent - Mild to moderate psoriasis (all types) with active plaques on both body sides accessible for biopsy and self product application - Age 18-60 years Exclusion Criteria: - Systemic psoriasis treatment 3 months prior and during the study - Local psoriasis treatment on the investigational sites in the last 30 days or during the study - Known hypersensitivity or allergy to the EGF containing product and/or to Vaseline/10% salicylic acid - History of malignant disease or another clinically relevant concomitant disease state - Participation in another investigational drug study in the last 30 days

Intervention groups

Patients are randomly selected. Two active plaques will be selected by a physician on two separate areas of the body. The intervention area will receive a cream containing 5% recombinant epidermal growth factor and another plaque will receive cream without epidermal growth factor as a control group.

Main outcome variables

Change to baseline in target lesion severity score (PASI)

General information

Reason for update

Acronym

EGF; EGFR

IRCT registration information

IRCT registration number: **IRCT20141007019432N8**
Registration date: **2022-03-12, 1400/12/21**
Registration timing: **prospective**

Last update: **2022-03-12, 1400/12/21**
Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Mohammadamir Amirkhani

Name of organization / entity

Skin and Stem Cell Research Center, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 1710

Email address

amirkhani@health.gov.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

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

Scientific title
Evaluation of topical adjuvant treatment of psoriasis with recombinant Epidermal Growth Factor to control the e-regulation of the Epidermal Growth Factor Receptor (EGFR): clinical trial phase 2

Public title
Epidermal Growth Factor adjuvant therapy for psoriasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Mild to moderate psoriasis (all types) with active plaques on both body sides accessible for self product application Age 18-60 years
Exclusion criteria:
Systemic psoriasis treatment 3 months prior and during the study Local psoriasis treatment on the investigational sites in the last 30 days or during the study Known hypersensitivity or allergy to the EGF containing product and/or to Vaseline/10% salicylic acid History of malignant disease Other clinically relevant concomitant disease state Participation in another investigational drug study in the last 30 days
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **21**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, this method is equivalent to tossing a coin for each subject that enters a trial, such as Heads = Active, Tails = Placebo. Implementation and treatment of assignments are completely unpredictable.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
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
Tehran University of Medical Sciences, Cross Qods st, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2021-11-28, 1400/09/07
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.962

Health conditions studied

1

Description of health condition studied
Psoriasis
ICD-10 code
L40
ICD-10 code description
Psoriasis

Primary outcomes

1

Description
Measure of Psoriasis Area and Severity Index (PASI)
Timepoint
before intervention and 1
Method of measurement
Psoriasis Area and Severity Index (PASI) based on the standard

Secondary outcomes

1

Description
Skin quality
Timepoint
Before intervention and 1
Method of measurement
Ultrasound skin imaging

Intervention groups

1

Description

Intervention group: The intervention group will receive a topical cream containing 5% recombinant epidermal growth factor, twice a day for a month.

Category

Treatment - Drugs

2

Description

Control group: the group will be received topical cream which is standard care containing: clobetasol 30gr, urea 15gr, distilled water 15 cc, salycilic acid 1.5 % and eucerin up to100gr, without epidermal growth factor, twice a day for a month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin & Stem Cell Research Center of Tehran University and Medical Sciences

Full name of responsible person

Mohammad Amir Amirkhani

Street address

Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran

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1937957511

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+98 21 2220 1710

Email

Amirkhani2000@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Nilforoushzadeh

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dr_nilforoush@yahoo.com

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

Dr. Mohammadamir Amirkhani

Position

Project Manager - Medical Doctor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

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Position

Project Manager - Medical Doctor

Latest degree

Ph.D.

Other areas of specialty/work
Medical Biotechnology
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Person responsible for updating data

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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 collected for the primary outcome
When the data will become available and for how long
data relative to the time after finishing the data collection and 3 months after publication
To whom data/document is available
available for people working in an academic institution
Under which criteria data/document could be used
There is no specific criteria
From where data/document is obtainable
People can send an email to get more information
What processes are involved for a request to access data/document
After requesting the data, you will get an email with information
Comments