

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

Mohammad Amir 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, salicylic 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+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

**Street address**

Kamraniyeh Ave., Maryam deadend,

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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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**Email**

amirkhani@health.gov.ir

**Web page address**

<http://311.rc.research.ac.ir/>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadamir Amirkhani

**Position**

Project Manager - Medical Doctor

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Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Amir Amirkhani

**Position**

Project Manager - Medical Doctor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Postal code**

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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**