

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of cyclosporine and etanercept on Toxic epidermal necrolysis

#### Protocol summary

##### Study aim

Comparison of the effect of Cyclosporine and Etanercept on patients with TEN in Loghman Hakim hospital from 1398 to 1399 Evaluation of response rate to the treatment based on level of re-epithelization Evaluation of response rate to the treatment based on total days of admission Evaluation of response rate to the treatment based on total days of admission in ICU

##### Design

This study is a clinical trial in phase 2-3, on two groups of patients with toxic epidermal necrolysis. The sample size calculated in each group is 20 persons. Once the diagnosis is confirmed by a dermatologist, treatment begins with one group receiving cyclosporine and the other with etanercept. Simple randomization is done using a random number table.

##### Settings and conduct

This study performed on patients with toxic epidermal necrolysis referred to Loghman Hakim Hospital in 2020-2021. After examination by a dermatologist Patients admitted at the ICU ward of Loghman Hakim Hospital for their treatment. Skin biopsies and tests are performed for the patients. Daily examinations are performed by the dermatologist and resident. The whole data are recorded in the patient's file.

##### Participants/Inclusion and exclusion criteria

Patients with toxic epidermal necrolysis confirmed by dermatologist.

##### Intervention groups

Patients admitted with the diagnosis of toxic epidermal necrolysis are randomly divided into two treatment groups. One group receives 3 mg/kg daily cyclosporine and a single dose of 50mg etanercept subcutaneously is administered to the other group at the time of admission to the hospital.

##### Main outcome variables

The rate of re-epithelialization in patients lesions in each group which is defined as not having new lesions and an 80% improvement in previous lesions. Number of days of

admission. Number of days of admission in ICU. Mortality rate of patients based on SCORTEN. Drugs complications in the patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191020045169N1**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **prospective**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

##### Registration date

2020-02-14, 1398/11/25

##### Registrant information

##### Name

farnaz araghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2290 0421

##### Email address

farnazaraghi@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of cyclosporine and etanercept on Toxic epidermal necrolysis

**Public title**  
Comparison of the effect of cyclosporine and etanercept on Toxic epidermal necrolysis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with toxic epidermal necrolysis confirmed by a dermatologist.  
**Exclusion criteria:**  
patients with any acquired or congenital immune deficiency. patients with stage 3 or 4 of heart failure. patients with uncontrolled hypertension. patients with renal failure. patients with known hypersensitivity to these drugs.

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple randomization by the table of random numbers.

**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 Shahid Beheshti University of Medical Sciences  
**Street address**  
Bldg No.2 SBUMS, Arabi Ave, Velenjak, Tehran, Tehran Province  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Approval date**  
2020-01-03, 1398/10/13  
**Ethics committee reference number**  
IR.SBMU.RETECH.REC.1398.478

## Health conditions studied

### 1

**Description of health condition studied**  
toxic epidermal necrolysis  
**ICD-10 code**  
L51.2  
**ICD-10 code description**  
Toxic epidermal necrolysis [Lyell]

## Primary outcomes

### 1

**Description**  
lesions re-epithelialization of the toxic epidermal necrolysis  
**Timepoint**  
daily, during patients admission  
**Method of measurement**  
by dermatologist examination and taking standard pictures from patients lesions

## Secondary outcomes

### 1

**Description**  
Mortality rate of the patients  
**Timepoint**  
During their admission in the hospital  
**Method of measurement**  
SCORTEN index

## Intervention groups

### 1

**Description**  
Intervention group: toxic epidermal necrolysis patients, treated with etanercept 50mg(Ariogen pharmed) single dose subcutaneously on their first day of admission  
**Category**  
Treatment - Drugs

### 2

**Description**  
Intervention group: Toxic epidermal necrolysis patients, treated with 3 mg/kg cyclosporine oral daily.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Loghman hakim hospital

**Full name of responsible person**

Mehdi Gheisari

**Street address**Makhsus St., Qazvin St., Tehran., Tehran Province.,  
Iran**City**

Tehran

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1333625445

**Phone**

+98 21 5541 9005

**Email**

loghman.hospital@sbmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin zarghi

**Street address**No.2., Arabi Ave., Velenjak., Tehran., Tehran  
Province., Iran.**City**

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1985717443

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info@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farnaz Araghi

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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Qazvin St., , Tehran., Tehran Province, Iran.**City**

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farnazaraghi@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mehdi Gheisari

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farnaz Araghi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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**Postal code**

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**Phone**

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**Email**

farnazaraghi@sbmu.ac.ir

## 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data is shareable after de-identification of participants.

**When the data will become available and for how long**

starting after publication for 6 months.

**To whom data/document is available**

People working in academic institutions

**Under which criteria data/document could be used**

This information will only be available to authors of review and meta-analysis articles with citation.

**From where data/document is obtainable**

Email address of corresponding author

**What processes are involved for a request to access data/document**

The application should be sent to the email address with the approval of the relevant academic institution and confirming of article citation should be submitted before sending data.

**Comments**