Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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@sbmu.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

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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

leisions 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
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Makhsus St., Qazvin St., Tehran., Tehran Province., Iran
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Sponsors / Funding sources

1

Sponsor
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No.2., Arabi Ave., Velenjak., Tehran., Tehran Province., Iran.
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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
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
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Dermatology resident
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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
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