Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of a single dose of estradiol valerate on the duration of hospitalization and its consequences in patients with severe burns: A clinical trial

Protocol summary

Study aim
Determining the effectiveness of estradiol valerate injection on the duration of hospitalization and its consequences in patients with severe burns in Rasht hospital in 1400.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. To generate random numbers, various packages available in R software will be used.

Settings and conduct
Rasht Province Hospital. Patient, researcher and evaluator of blindness And samples are randomly selected

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient with severe burns (second or higher degree burns with an area of more than 20%) Acute burns which have occurred in less than 24 hours. Fill out the informed consent form exclusion criteria: electric burns Inhalation burns People undergoing hormone therapy. People with a history of estrogen-dependent cancer (breast, uterus, ovary). Pregnants

Intervention groups
Both groups receive standard burn treatment. The intervention group will receive standard treatment with estradiol valerate. The control group will receive standard treatment.

Main outcome variables
Discharge time and speed of recovery (seen daily)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210524051384N7**
Registration date: **2021-11-23, 1400/09/02**
Registration timing: **prospective**

Last update: **2021-11-23, 1400/09/02**
Update count: **0**

Registration date
2021-11-23, 1400/09/02

Registrant information
Name
mohammadreza mobayen
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 13 3336 8540
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of a single dose of estradiol valerate on the duration of hospitalization and its consequences in patients with severe burns: A clinical trial

Public title
Evaluation of a single dose of estradiol valerate on the

duration of hospitalization and its consequences in patients with severe burns: A clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with severe burns (second or higher degree burns with an area of more than 20%) Fill out the informed consent form Acute burns have occurred in less than 24 hours.

Exclusion criteria:

Electric burns Inhalation burns People with a history of estrogen-dependent cancer (breast, uterus, ovary) Pregnant and lactating people taking phenobarbital, carbamazepine, ritonavir, rifampin, People with a history of thrombophlebitis and thromboembolism.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in order to assign patients to intervention and control groups, the restricted randomization approach will be used in the form of block randomization. Blocking is commonly used to balance the number of samples assigned to each of the study groups. This method during sampling causes the sample assigned to each of the study groups to be equal. To prevent the last allocation from being detected in the blocks under consideration, we will consider the size of the blocks to be random with a size of 4 or 6.Various packages in R software will be used to generate random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants (patients) would be blinded by sealed envelopes. It should be noted that each created randomized sequences will be recorded on a card, and the cards will be put inside the envelopes respectively. In order to blind researcher, similar syringes, the same color injection solutions for the control and intervention groups will be used. The analyzer will also be blinded according to coding of envelope and syringes .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Guilan University of Medical Sciences

Street address

Namjoo St., Velayat Hospital (3rd floor), Clinical Development Center

City

rasht

Province

Guilan

Postal code

4144666949

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.GUMS.REC.1400.358

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

Discharge time and speed of recovery

Timepoint

daily

Method of measurement

Based on patients' records

Secondary outcomes

1

Description

Discharge status

Timepoint

daily

Method of measurement

view of patient file

2

Description

Duration of hospitalization in the ICU

Timepoint

daily

Method of measurement

patient record

3

Description

Comparison of changes in inflammatory factor IL-6

Timepoint

on day 1 (before injection of estradiol valerate) and 3 and 7

Method of measurement

ELISA

4

Description

Itching rate

Timepoint

daily

Method of measurement

based on the patient's statements

5

Description

Comparison of changes in laboratory indices of serum levels of CRP, ferritin, LDH, CPK

Timepoint

On days 1, 3 and 7

Method of measurement

By laboratory kits

6

Description

INR, PT, PTT

Timepoint

On days 1, 3 and 7

Method of measurement

By laboratory kits

7

Description

Serum and blood transfusion

Timepoint

daily

Method of measurement

based on patient records

Intervention groups

1

Description

Intervention group: Intervention group: Intervention group: Patients receiving estradiol valerate upon arrival after receiving consent, standard treatment and single dose of estradiol valerate (manufactured by Abu Reihan factory, Iran) at a dose of 0.5 ml / kg intramuscularly, none Patients included in the study (both intervention group and control group) will not be deprived of routine treatment of burn patients.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive standard treatment. None of the patients included in the study (both intervention group and control group) will be deprived of routine treatment of burn patients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

velayat hospital

Full name of responsible person

Dr. Mohammad Reza Mobin

Street address

Namjoo Street, Velayat Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipour

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Namjoo St., in front of 17 Shahrivar Hospital, Deputy of Research and Technology

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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Mobayen
Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu
Latest degree
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Person responsible for updating data

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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