

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Levamisole effect on mortality reduction in patients with more than 50% burn of body surface area

#### Protocol summary

##### Summary

The effect of Levamisole on improvement of immune system is well known. Obviously, infection is one of the major causes of death in burned patients. If this drug could reduce the infection rates in burn victims, then the mortality rate would also be decreased. One hundred patients with more than 50%, 3rd degree burn of body surface area are randomly divided into two groups. Patients with electrical or chemical burns, medical illness or on chronic use of medications are excluded from the study. The hospital care for all patients is the same as for the standard medical and surgical treatments. In group one Levamisole 100 mg/day is added to the treatment plan. In group two this drug is not administrated. Age, sex, cause of burn, percentage of burn area, burn degree, and specific body area, mortality, hospital stay, operation frequency and blood transfusion are evaluated and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903044020N1**

Registration date: **2010-07-23, 1389/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-07-23, 1389/05/01

##### Registrant information

###### Name

Mohamad Javad Fatemidokht

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8870 8415

###### Email address

mjfeh@iums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Iran university of medical sciences

###### Expected recruitment start date

2010-07-23, 1389/05/01

###### Expected recruitment end date

2011-07-23, 1390/05/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Levamisole effect on mortality reduction in patients with more than 50% burn of body surface area

###### Public title

Levamisole effect on mortality reduction in patients with more than 50% burn of body surface area

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: patients that are admitted within 24 hours after burn with more than 50%, 3rd degree burn of body surface area. Exclusion criteria: patients who are admitted after 24 hours or treated in other centers before admission in hospital; patients with electrical or chemical burns, medical illness or on chronic use of medications.

###### Age

No age limit

###### Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences

##### Street address

Hemmat Highway

##### City

Tehran

##### Postal code

5983-14155

#### Approval date

2010-01-05, 1388/10/15

#### Ethics committee reference number

896

## Health conditions studied

### 1

#### Description of health condition studied

Burns over 50%

#### ICD-10 code

T20-T25

#### ICD-10 code description

Burns and corrosions of external body surface, specified by site

### 2

#### Description of health condition studied

Burns over 50%

#### ICD-10 code

T26-T28

#### ICD-10 code description

Burns and corrosions confined to eye and internal organs

### 3

#### Description of health condition studied

Burns over 50%

#### ICD-10 code

T29-T32

#### ICD-10 code description

Burns and corrosions of multiple and unspecified body regions

## Primary outcomes

### 1

#### Description

Mortality

#### Timepoint

Daily

#### Method of measurement

Died in hospital due to complications of burns

## Secondary outcomes

### 1

#### Description

Hospital stay

#### Timepoint

daily

#### Method of measurement

From start to completion of admission

### 2

#### Description

Visit surgery

#### Timepoint

daily

#### Method of measurement

no. of transferring to the operating room

### 3

#### Description

The need for blood transfusion

#### Timepoint

daily

#### Method of measurement

Volume transfused during hospitalization

## Intervention groups

### 1

#### Description

Levamisole, 100 mg, daily in oral form

#### Category

Treatment - Drugs

### 2

#### Description

no intervention in control group

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Center of medical education and treatment of Hazrat fatemeh

**Full name of responsible person**

Mohamad Javad Fatemidokht

**Street address**

Street 21, Jamal al-Din Asad Abadi Avenue

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Abbas Motevaliyan

**Street address**

Hemat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Iran University Of Medical Sciences

**Full name of responsible person**

Mohamad Javad Fatemidokht

**Position**

Plastic and reconstructive surgeon, Associated professor

**Other areas of specialty/work**

**Street address**

Hazrat fatemeh hospital, 21 St., Seyed Jamaledin Asad Abadi Ave.

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**Position**

Plastic and reconstructive surgeon, Associated professor

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**Full name of responsible person**

Pegah Nafar

**Position**

BS Biology

**Other areas of specialty/work**

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istatis\_pn@yahoo.com , mjfch@iums.ac.ir ,  
fatemi41@yahoo.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*