

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of Methyl Prednisolone preventive effects in Fat Embolism Syndrome on Patients with Fracture of Long Bones

#### Protocol summary

##### Summary

Study of preventive Effects of Methyl Prednisolone in Fat Embolism Syndrome on Patients with Fracture of Long Bones that will be done on 94 patients with closed fractures of tibia or femur during their admission in hospital. patients with skull, chest, lungs, pelvic, diaphragm, urogenital injuries and... will be excluded. patients will be placed in two 47 patients category randomly by block randomization. patients will be intravenously injected by methylprednisolone or placebo (N/S) three times at the beginning and then every 4 hours with the dosage of 10 mg/kg. All the patients will be examined at 0, 12, 24, 72 hours after the admission and body temperature, heart rate, blood pressure, respiratory rate and Arterial blood gases will be measured. Outcomes we studied are based on Lindeque criteria that includes respiratory parameters: 1-  $p_{aO_2} < 60$  mmHg 2-  $p_{aCO_2} > 55$  mmHg 3- respiratory rate  $> 35$  after good sedation 4- dyspnea, tachypnea. based on this criteria patients who has one or more of these parameters are diagnosed fat emboli syndrome

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013101311898N6**  
Registration date: **2014-12-24, 1393/10/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-24, 1393/10/03

##### Registrant information

Name

Ahmadreza Mirbolouk

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 2250

##### Email address

ah.mirbolouk@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Guilan University of Medical Sciences

##### Expected recruitment start date

2014-12-03, 1393/09/12

##### Expected recruitment end date

2015-01-02, 1393/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of Methyl Prednisolone preventive effects in Fat Embolism Syndrome on Patients with Fracture of Long Bones

##### Public title

Study of Methyl Prednisolone effects on fat emboli in the patients with fractures

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with closed fractures of femur or tibia that refers to Poursina hospital  
Exclusion criteria: patients with skull, chest, lungs, pelvic, diaphragm, urogenital injuries and pathologic fracture, pregnant women, history of cardiac

and lung disease or a history of corticosteroid treatment will not be included in

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 94

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research and Technology Department of Guilan University of Medical Sciences

##### Street address

Next to Iranradiator Building, Gaz Square, Rasht

##### City

Rasht

##### Postal code

##### Approval date

2014-11-25, 1393/09/04

##### Ethics committee reference number

1930400402

## Health conditions studied

### 1

#### Description of health condition studied

Fat Embolism

#### ICD-10 code

t79.1

#### ICD-10 code description

Fat embolism (traumatic)

## Primary outcomes

### 1

#### Description

pco2>55mmhg

#### Timepoint

first visit,12h,24h,72h after admission

#### Method of measurement

mmhg, lab tests

### 2

#### Description

po2<60 mmhg

#### Timepoint

first visit,12h,24h,72h after admission

#### Method of measurement

mmhg, lab tests

### 3

#### Description

respiratory rate>35 per minute

#### Timepoint

first visit,12h,24h,72h after admission

#### Method of measurement

clinical examination

### 4

#### Description

dyspnea, Tachypnea

#### Timepoint

first visit,12h,24h,72h after admission

#### Method of measurement

clinical examination

## Secondary outcomes

### 1

#### Description

Acidotic Arterial blood PH

#### Timepoint

first visit, 12h,24,72 h after admission

#### Method of measurement

Lab test(ABG)

## Intervention groups

### 1

#### Description

intravenously injection of Methyl prednisolone with the dosage of 10 mg/kg every 4 hours during 72 h of admission

#### Category

Treatment - Drugs

### 2

#### Description

intravenously injection of placebo(normal saline) with the dosage of 10 mg/kg every 4 hours during 72 h of

admission  
**Category**  
Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Poursina hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Rasht

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Research and Technology Department of Guilan  
University of Medical Sciences  
**Full name of responsible person**  
Abtin Heidarzadeh (Specialist)  
**Street address**  
Reaserch and Technology Building next to Iran  
Radiator Building, Gaz Square, Rasht  
**City**  
Rasht

### Grant name

### Grant code / Reference number

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

### Title of funding source

Research and Technology Department of Guilan  
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**  
Research and Technology Department, Guilan  
University of Medical Sciences  
**Full name of responsible person**  
Mohammad Sadeq Mousavi  
**Position**  
Medical Student  
**Other areas of specialty/work**

### Street address

Poursina Hospital, Higher than the Census Bureau,  
Poursina intersection

### City

Rasht

### Postal code

### Phone

+98 13 3355 2241

### Fax

### Email

arman.mousavi1989@gmail.com

### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Guilan University of Medical Sciences

### Full name of responsible person

DR.Hossien Ettehad

### Position

Orthopaedic surgeon

### Other areas of specialty/work

### Street address

Poursina Hospital, Higher than the Census Bureau,  
Poursina intersection

### City

rasht

### Postal code

### Phone

+98 13 3355 2241

### Fax

### Email

h.ettehad70@gums.ac.ir

### Web page address

## Person responsible for updating data

### Contact

### Name of organization / entity

Orthopaedic Research Center of Guilan University of  
Medical Sciences

### Full name of responsible person

Milad Shoa Kazemi

### Position

Medical student

### Other areas of specialty/work

### Street address

### City

### Postal code

### Phone

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### Fax

### Email

miladkazemi\_1367@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*