

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 exclude. patients will be placed in two 47 patients category randomizely by block randomization. patients will be intravenously injected by methylprednisolon or placebo(N/S)three times at the begining and then every 4 hours with the dosage of 10 mg/kg. All the patients will be examine at 0,12,24,72 hours after the admission and body temprature, heart rate, blood pressure, respiratory rate and Arterial blood gases will be mesured .outcomes we studies are based on lindeque criterias that includes respiratory parameters: 1-pao₂<60 mmhg 2-paco₂>55 mmhg 3-respiratory rate>35 after good sedation 4-dyspnea, tachypnea. based on this criteria patients who has one or more of this 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)

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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,
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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

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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

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00

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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