

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Alterations in serum inflammatory markers in patients under early and late surgery for femoral fractures

Protocol summary

Study aim

The main purpose of this study is determination of alterations in serum level of inflammatory markers of interferon Gamma and interleukins 1, 5, and 6, and TNF-Alpha that would be measured at baseline and after one hour from surgery among patients with femoral fracture under early versus late surgery.

Design

Randomised, superiority, parallel group trial with blinded outcome assessment

Settings and conduct

Rasool Hospital , Sattarkhan Street

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fracture of femoral shaft and aging from 20 to 50 years

Intervention groups

Patients with femoral fracture in the 2 groups were under the same surgery, before 24 hours of the visit to the hospital and after 24 hours of a visit to the hospital

Main outcome variables

TNF-Alpha , Interleukin 6 , interleukin 5 , interleukin 1 , INF gama

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110519818N1**

Registration date: **2015-01-03, 1393/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-09, 1397/09/18**

Update count: **1**

Registration date

2015-01-03, 1393/10/13

Registrant information

Name

Mehdi Moghtadaei

Name of organization / entity

Rasool Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2264

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moghtadaei.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

2015-01-01, 1393/10/11

Actual recruitment end date

2015-09-19, 1394/06/28

Trial completion date

2015-10-23, 1394/08/01

Scientific title

Alterations in serum inflammatory markers in patients under early and late surgery for femoral fractures

Public title

Inflammation in femoral fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fracture of femoral shaft no any other concomitant injury aging from 20 to 50 years

Exclusion criteria:

Presence of concomitant injuries presence of chronic inflammatory diseases

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

double blind , That is not the patient knew which group under the surgery and not see any sick doctor knew when and what time the surgery group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Rasool Hospital

Street address

Sattarkhan Street

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

93/912

Health conditions studied**1****Description of health condition studied**

Fracture of shaft of femur

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

Primary outcomes**1****Description**

Interferon Gamma

Timepoint

one hour after surgery

Method of measurement

Lab Kit

2**Description**

Interleukin 1

Timepoint

one hour after surgery

Method of measurement

Lab Kit

3**Description**

Interleukin 5

Timepoint

one hour after surgery

Method of measurement

Lab Kit

4**Description**

Interleukin 6

Timepoint

one hour after surgery

Method of measurement

Lab Kit

5**Description**

TNF-Alph

Timepoint

one hour after surgery

Method of measurement

Lab Kit

Secondary outcomes**1****Description**

Interlukin 1

Timepoint

One hour after surgery
Method of measurement
Lab Kit

2

Description
IFN-Gamma
Timepoint
One hour after surgery
Method of measurement
lab kit

3

Description
TNF-Alpha
Timepoint
one hour after surgery
Method of measurement
lab kit

4

Description
interlukin 5
Timepoint
one hour after surgery
Method of measurement
lab kit

5

Description
interlukin 6
Timepoint
one hour after surgery
Method of measurement
lab kit

Intervention groups

1

Description
all patients with fractures of the femur bone that before 24 hours of admission to the emergency room, a common method of surgery are located and The fracture is fixed only by the plate
Category
Treatment - Surgery

2

Description
all patients with fractures of the femur bone that After 24 hours of admission to the emergency room, a common method of surgery are located and The fracture is fixed only by the plate
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Hospital
Full name of responsible person
Dr.Babak Otoukesh
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babak.otoukesh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Malakouti Seyed Kazem
Street address
Hemmat Exp Way, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
PR@iums.ac.ir
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
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

Iran University of Medical Sciences

Full name of responsible person

Dr. Babak Otoukesh

Position

Orthopedics Surgeon

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Web page address

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Just part of the original data, such as information related to the outcome or the possibility of sharing it

When the data will become available and for how long

Access the course start 6 months after printing the results

To whom data/document is available

Just for researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used

Only the fields of data use is possible

From where data/document is obtainable

Dr. Babak otoukesh to the following phone and email address be referred babak.otoukesh@gmail.com +989126843678

What processes are involved for a request to access data/document

After reviewing the request will be answered within a maximum of 1 month

Comments

The result of this research paper has been published and accessible to the public via the link below :

<https://www.termedia.pl/Evaluation-of-inflammatory-resp>

[onse-in-patients-undergoing-surgical-treatment-for-early-and-delayed-femoral-fractures,19,28559,1,1.html](https://www.termedia.pl/Evaluation-of-inflammatory-resp-onse-in-patients-undergoing-surgical-treatment-for-early-and-delayed-femoral-fractures,19,28559,1,1.html)