Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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-Alph , Interleukin 6 , interlukin 5 , interlukin 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

Email address
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
Street address
sattarkhan street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6655 9595
Email
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
Street address
Sattarkhan Street, Rasool Hospital, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+216 6516001
Fax
Email
babak.otoukesh@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasool Hospital
Full name of responsible person
Babak Otoukesh
Position
Orthopedic Surgeon
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6651 6001
Fax
Email
babak.otoukesh@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran university of medical sciences
Full name of responsible person
Babak Otoukesh
Position
Orthopeics Surgeon
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Sattarkhan Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14456131
Phone
+216 6516001
Fax
Email
babak.otoukesh@gmail.com
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-response-in-patients-undergoing-surgical-treatment-for-early-and-delayed-femoral-fractures,19,28559,1,1.html