

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Comparison of the results of two methods of autograft and allograft in trauma patients with long-bone fractures referred to orthopedic ward in the Shahid Beheshti hospital Babol

Protocol summary

Study aim

Choosing the right graft method for long bone fractures

Design

In this study, 100 patients have been assigned to two groups of intervention and control by using random numbers table.

Settings and conduct

In this clinical trial, all patients who undergo bone graft surgery in Shahid Beheshti Hospital with upper and lower extremity bone fractures diagnosis include the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient willingness, Having genetic disorders and other skeletal deformities in the organs that affect the outcome of the study, Having Systemic Disease Like: Metabolic Diabetes, Split fractures of diaphyseal bone with long bones without general or specific bone disease, Lack of brain trauma. Exclusion criteria: Systemic underlying disease, such as diabetes, bone underlying disease, such as bony cysts, Head injury, Lack of timely referral for follow-up therapy to the orthopedic clinic.

Intervention groups

One group was treated with conglomerate autograft and another group with allografts of cancellous chips.

Main outcome variables

Rate of union; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160508027797N3**

Registration date: **2018-05-26, 1397/03/05**

Registration timing: **retrospective**

Last update: **2018-05-26, 1397/03/05**

Update count: **0**

Registration date

2018-05-26, 1397/03/05

Registrant information

Name

Masoud Bahrami Ferydoni

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

m.bahrami@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-23, 1395/04/03

Expected recruitment end date

2017-06-24, 1396/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of two methods of autograft and allograft in trauma patients with long-bone fractures referred to orthopedic ward in the Shahid Beheshti hospital Babol

Public title

Comparison of the results of two methods of autograft and allograft in trauma patients with long-bone fractures

referred to orthopedic ward in the Shahid Beheshti hospital Babol

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient Satisfaction to Participate in this Study Not having genetic disorders and other skeletal deformities in the organs that affect the outcome of the study. Not having systemic illness like: diabetes mellitus Split fractures of diaphyseal bone with long bones without general or specific bone disease Lack of brain trauma
Exclusion criteria:
In cases of systemic underlying disease, such as diabetes, bone underlying disease such as bony cysts Head injury Lack of timely referral for follow-up therapy to the orthopedic clinic

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be divided into two groups of autograft and allograft using Permuted Block Randomization. Number will be selected for allocation concealment by one of the colleagues and by another, that assignment chain is chosen.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province

Mazandaran
Postal code
4716681451
Approval date
2017-11-18, 1396/08/27
Ethics committee reference number
MUBABOL.HRI.REC.1396.89

Health conditions studied

1

Description of health condition studied

Long bone fracture

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

Rate of union

Timepoint

Three and Six months after the end of the intervention

Method of measurement

Serial radiography from fracture area

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:open reduction, Allograft, this is ready made that will be purchased from the providing company and there is no need for iliac crest surgery

Category

Treatment - Surgery

2

Description

Control group: open redaction, iliac bone graft (Autograft)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Beheshti Hospital

Full name of responsible person

Dr. Masoud Bahrami Ferydoni

Street address

Babol University of Medical Sciences; Ganjafrooz
Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Drbahrami865@gmail.com

Position

Orthopedic Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrooz
street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Hamid_va@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Babol University of Medical Sciences; Ganjafrooz
Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4

Phone

+98 11 3219 7667

Email

Hamid_va@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Valiollahpour Amiri

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Masoud Bahrami Ferydoni

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrooz
Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Drbahrami865@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Valiollahpour Amiri

Position

Orthopedic Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrooz
Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Hamid_va@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available