Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluating the Efficacy of Intra-articular Injection of High molecular weight Hyaluronic Acid on the Knee Performance of Patient with Tibial Plateau Fracture after Surgical Intervention

Protocol summary

Study aim

Evaluating the Efficacy of Intra-articular High Molecular Weight Hyaluronic Acid Injection on the Knee Performance of Patient with Tibial Plateau Fracture after Surgical fixation

Design

This is a randomized, triple blinded, placebo control, clinical trial with two parallel groups.

Settings and conduct

Participants received intra-Articular injection by an orthopedic surgeons who were not involved in other aspects of this investigation. Participants, investigators, outcome assessors, data analyst and patients were blinded.

Participants/Inclusion and exclusion criteria

Included participants were adults (18-65 years old), who had tibial plateau fracture and were candidates for fixation operation and signed the informed consent Excluded patients were pregnant and nursing mothers, past medical history of diabetes mellitus, severe osteoarthritis, sever osteoporesis, those who were not candidates for surgical fixation (Active septic disorders of knee joint and tissues around the knee, coagulopathies, active rheumatologic disorders, Heart Failure, Chronic obstructive pulmonary disease, ...), those with open fractures and those with failure to perform internal fixation due to extensive tissue damage

Intervention groups

All participants received 2 injections with 2 weeks interval, the first injection was done 2 weeks after fixation operation have done. Intervention group received 2 ml high molecular hyaluronic acid (Synogel) contained 32 mg in 2 ml and placebo group received 2 ml normal saline in each injection.

Main outcome variables

Pain and knee function were assessed by Visual Analogue Scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Score) in zero point (2 weeks after fixation operation), 2 weeks and 22 weeks after, and also the range of motion was assessed by goniometre.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170608034390N3**
Registration date: **2019-06-13, 1398/03/23**
Registration timing: **retrospective**

Last update: **2019-06-13, 1398/03/23**
Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Hadi Esmaily

Name of organization / entity

SBMU

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-16, 1397/02/26

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date
2018-05-22, 1397/03/01
Actual recruitment end date
2019-01-20, 1397/10/30
Trial completion date
2019-06-20, 1398/03/30

Scientific title
Evaluating the Efficacy of Intra-articular Injection of High molecular weight Hyaluronic Acid on the Knee Performance of Patient with Tibial Plateau Fracture after Surgical Intervention

Public title
Assessing the Efficacy of Intra-articular Injection of High Molecular Weight Hyaluronic Acid on Knee Function of Patients with Tibial Plateau Fracture after Surgical Fixation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (18-65 years) Tibial Plateau Fracture Signing the Informed Consent
Exclusion criteria:
Pregnancy & Lactation Diabetes Mellitus Severe osteoarthritis Sever Osteoporesis Non-surgical patients (Active septic disorders of knee joint and tissues around the knee, Coagulopathies, Active rheumatologic disorders, Heart Failure, COPD, ...) Open fractures Failure to perform internal fixation due to extensive tissue damage
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

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

Sample size
Target sample size: **32**
Actual sample size reached: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
With block randomization and allocation the patients into eight blocks with four patients in each group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
All Participants, Investigators, Outcome assessors, Data analyst and quality controller are blinded, however as the viscosity of the Hyaluronic Acid are dramatically higher than normal saline solution used as placebo, it was impossible to blind the practitioner who will do the injections, so an independent physician handled the injections.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National ethics ommittee for biomedical research
Street address
Central Department of Ministerial of Health and Medical Education, Sima Iran St, between South Falamak and Zarafshan St, Shark Gharb
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2018-05-15, 1397/02/25
Ethics committee reference number
IR.SBMU.MSP.REC.1397.222

Health conditions studied

1

Description of health condition studied
Tibial Plateau Fracture
ICD-10 code
S82.1
ICD-10 code description
Fracture of upper end of tibia

Primary outcomes

1

Description
Pain by Visual Analogue Scale (VAS) score
Timepoint
Starting point, 2 and 22 weeks after first Injection
Method of measurement
Using standard scale for VAS score

Secondary outcomes

1

Description
Range of Motion

Timepoint
Starting point (2 weeks after fixation operation), 2 and 22 weeks after first Injection
Method of measurement
Using goniometer

2

Description
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Score)
Timepoint
Starting point, 2 and 22 weeks after first Injection
Method of measurement
Using validated questionnaire of WOMAC Score

Intervention groups

1

Description
Control group:intra-articular injections of 2 ml Normal Saline in 2, 4 weeks after surgery, under sterile conditions and by an orthopedic specialist
Category
Placebo

2

Description
Intervention group: intra-articular injections of 2 ml High Molecular Weight Hyaluronic Acid in 2, 4 weeks after surgery, under sterile conditions and by an orthopedic specialist
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Habib Malekpour
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Madani Ave, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Shahid Beheshti university of medical sciences, Shahid Arabi St, Yemen Ave, Shahid Charman Highway
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi Esmaily
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The whole potential data is unpublished after being unidentifiable.

When the data will become available and for how long
Start the access period 6 months after printing the results.

To whom data/document is available
Researchers working in academic and industrial institutions.

Under which criteria data/document could be used
Researchers working in academic and industrial institutions.

From where data/document is obtainable
Dr. Hadi Esmaily, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences.

What processes are involved for a request to access data/document
After sending a request it will be available

Comments