Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effectiveness of the PLGA(poly lactic Co-glycolic acid) system loaded with Deferoxamine with Core decompression alone in treatment of patients with early stage of Osteonecrosis of the femur head

Protocol summary

Study aim
Evaluation of the efficacy of Core Decompression (CD) with PLGA loaded with deferoxamine in recovery of patients with early stage of osteonecrosis of the femoral head(ONOFH)

Design
Clinical trial with control group with parallel groups and Randomized method is simple and using random number table

Settings and conduct
Patients who come to the Shafa Yahyaian Hospital with hip pain and ONOFH is diagnosed After checking the inclusion and exclusion criteria and obtaining consent, they will be included in the study.

Participants/Inclusion and exclusion criteria
Age > 18 Patients with early stages of ONFH Association Research Circulation Osseous (ARCO) stage 1 or 2 Idiopathic, steroid and alcohol induced, associated with lupus and sickel cell anemia

Intervention groups
Patients in the intervention group after admission in the operating room according to the location of the osteonecrosis with fluoroscopy guide will first be placed under the CD, and immediately the PLGA -defroxamine system will be placed in the same place. Patients in the control group after admission in the operating room according to the location of the osteonecrosis with fluorescope guide will be only under the CD at the specified location .

Main outcome variables
Femoral head necrosis rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161121031003N3**
Registration date: **2019-04-16, 1398/01/27**
Registration timing: **retrospective**

Last update: **2019-04-16, 1398/01/27**
Update count: **0**

Registration date
2019-04-16, 1398/01/27

Registrant information

Name
Kaveh Gharanizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3354 2000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effectiveness of the PLGA(poly

lactic Co-glycolic acid) system loaded with Deferoxamine with Core decompression alone in treatment of patients with early stage of Osteonecrosis of the femur head

Public title
Effect of PLGA(poly lactic Co-glycolic acid) system loaded with Deferoxamine in Osteonecrosis of the femur head

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age > 18 years ARCO stage 1 or 2 Idiopathic, steroid and alcohol induced, associated with lupus and sickel cell anemia

Exclusion criteria:
Age> 50 years previous history of pelvic surgery An underlying condition that prevents surgery such as heart or lung disease

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized method is simple and using random number table, patients are divided into two groups: intervention and control

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 Iran University of Medical Sciences

Street address
Mojahedin eslam

City
tehran

Province
Tehran

Postal code
1449614535

Approval date
2019-01-26, 1397/11/06

Ethics committee reference number
IR.IUMS.FMD.REC.1397.281

Health conditions studied

1

Description of health condition studied
osteonecrosis of the femoral head

ICD-10 code
M91.9

ICD-10 code description
Juvenile osteochondrosis of hip and pelvis, unspecified

Primary outcomes

1

Description
Femoral head necrosis rate

Timepoint
At the beginning of the study (before the intervention) and 6 months and 12 months after the intervention, the hip joint MRI will be performed.

Method of measurement
MRI

Secondary outcomes

1

Description
Clinical status of patients

Timepoint
All patients will be examined prior to the intervention and at intervals of 2 weeks and 1-3-6 and 12 months after the intervention

Method of measurement
modified merle dAubigne scale

2

Description
pain

Timepoint
All patients will be examined prior to the intervention and at intervals of 2 weeks and 1-3-6 and 12 months after the intervention

Method of measurement
visual analog score

3

Description
cysts and subchondral sclerosis

Timepoint
All patients will be examined prior to the intervention and at intervals of 2 weeks and 1-3-6 and 12 months

after the intervention

Method of measurement

pelvic radiography

4

Description

The amount of collapse in femural head

Timepoint

At the beginning of the study (before the intervention) and 6 months and 12 months after the intervention

Method of measurement

Pelvic CT Scane

Intervention groups

1

Description

Intervention group: Patients in the intervention group after admission in the operating room according to the location of the osteonecrosis indicated in radiography, MRI and CT Scan with fluoroscopy guide will first be placed under the core decopression, and immediately the PLGA -defroxamine system will be placed in the same place. to prepare the PLGA -defroxamin system In this study, a scaffold of PLGA with a molecular weight of 25 kilodalton from Sigma Company is prepared using salt-leaching technique. Then, on each PLGA scaffold, 500 miligrams of dexroxamine are loaded.

Category

Treatment - Surgery

2

Description

Control group: Patients in the control group after admission to the operating room according to the location of the osteonecrosis indicated in the radiography, MRI and CT scan with fluorescope guide will be located only under the core decopression at the specified location

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Sajad noori Garavand

Street address

Mojahedin Eslam St, District 12, Tehran,Tehran Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Sajad Noori Garavand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Doctor Mohammad Ali Sharifi
Position
pharmacologist/ faculty member of Iran university of medical scienses
Latest degree
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Other areas of specialty/work
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Latest degree
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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
All information in both groups includes changes in MRI, CT Scan and radiography, as well as changes in VAS and modified merle dAubigne scale Publishable.
When the data will become available and for how long
after collect all data
To whom data/document is available
for all of the people
Under which criteria data/document could be used
no special condition
From where data/document is obtainable
Shafa Yahyayian hospital library .Mojahedin eslam street ,Baharestan square Email: sajadnoori85@yahoo.com Email: gharanizadeh.k@iums.ac.ir
What processes are involved for a request to access data/document
Email to mentioned address .In the libarary of Shafayahyayian hospital ,thesis of Dr.Sajad Noori Garavand
Comments