

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 Gharanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2000

Email address

gharanizadeh.k@iums.ac.ir

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 femoral 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 decompression, 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 milligrams 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 fluoescopre guide will be located only under the core decompression 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

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 3354 2005

Email

gharanizadeh.k@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Sajad Noori Garavand

Street address

Mojahedin Eslam St, District 12, Tehran,Tehran Province

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 3354 2005

Email

gharanizadeh.k@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

Sajad Noori Garavand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Mojahedin Eslam St, District 12, Tehran,Tehran

Province
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 3354 2005
Email
Gharanizadeh.k@iums.ac.ir

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 sciences
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Iran University of Medical Sciences, Between Chamran and Sheikh Fazlallah, hemmat highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 3354 2000
Fax
Email
Sharifalim@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
Sajad Noori Garavand
Position
Resident
Latest degree

Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Mojahedin Eslam St, District 12, Tehran, Tehran Province
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 3354 2005
Fax
Email
sajadnoori85@yahoo.com

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 library of Shafayahyayian hospital ,thesis of Dr.Sajad Noori Garavand

Comments