

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the Role of Silicone Therapy on Clinical and Radiological Symptoms in Patients with Idiopathic Osteonecrosis of the Femoral Head. A Clinical Trial study.

Protocol summary

Study aim

The study of the results of using Shoe inserts in patients with ION of femoral head referred to Hip Clinic of Shohada Hospital of Tabriz in 2017-2018.

Design

Randomised clinical trial

Settings and conduct

In this study, in coordination with other masters of Tabriz Shohada Hospital, referrals of patients, adult patients referred to the hip clinic with Femoral head ION diagnosis will be studied. First, patients who are not willing to undergo surgery will be divided into control and intervention groups. In this group In addition to all the usual therapies, shoe's insert will be prescribed, and in the the control group only the usual therapeutic will be taken. In this study, patients classified in FICAT Stage 1 and 2 will be included in the study and will not be included in patients undergoing surgery for the ION in the past year. In this study, each patient will be monitored and studied for one year. Due to the necessity of frequent referral to follow up, for each patient referral, the forms of HHS and FICAT will be filled in for analysis. That's why this research may require one and a half years to collect data.

Participants/Inclusion and exclusion criteria

Patients with ION of the femoral head that won't surgery procedures. But if they want, they will be deleted from the study.

Intervention groups

Patients with ION of the femoral head that use shoe inserts

Main outcome variables

Standard forms FICAT and HHS and shoe's insert

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040468N1**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **retrospective**

Last update: **2019-07-20, 1398/04/29**

Update count: **0**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

Mahdi Pashazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3381 7016

Email address

dr.m.pashazadeh.85@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2019-06-22, 1398/04/01

Scientific title

Investigating the Role of Silicone Therapy on Clinical and

Radiological Symptoms in Patients with Idiopathic Osteonecrosis of the Femoral Head. A Clinical Trial study.

Public title

medical insert in patients with osteonecrosis of the femur head

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Dissatisfaction with surgery

Exclusion criteria:

Failure to perform hip surgery in the past year

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **17**

Actual sample size reached: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in coordination with other masters of Tabriz Shohada Hospital, referrals of patients, adult patients referred to the hip clinic with Femoral head ION diagnosis will be studied. First, patients who are not willing to undergo surgery will be divided into control and intervention groups. In this group In addition to all the usual therapies, shoe's insert will be prescribed, and in the the control group only the usual therapeutic will be taken. In this study, patients classified in FICAT Stage 1 and 2 will be included in the study and will not be included in patients undergoing surgery for the ION in the past year. Of course, if during the course of the study, patients in either group need to undergo a surgical procedure will do. Femoral head ION may have different causes, and patients have been suffering from this disease for several reasons, and factors such as the use of Drugs, smoking, the amount of daily activity, alcohol consumption, and various types of ION-causing illnesses are considered as confounding factors in the study. However, by random categorization of patients between the two groups, this problem will be addressed in the study In this study, each patient will be monitored and studied for one year. Due to the necessity of frequent referral to follow up, for each patient referral, the forms of HHS and FICAT will be filled in for analysis. That's why this research may require one and a half years to collect data. Shoe's insert is designed for each patient in the center of the orthosis of Tabriz Shohada Hospital. Due to the fact that the use of medical flooring is not a proven method, the cost of the treatment is costly from the patient organization It is necessary to explain that in this study, none of the patients will know about the prescribing of shoe's insert to others, and because of the interpretation of the results based on the radiographic changes in the disease and standard scores,

there is no need for researchers to blind. Considering that no similar studies have ever been done in this regard, "all patients referred to the Shohada Hospital Hip Clinic will be studied within six months, and the sampling will continue until the end of the period. Subsequently, the sampling volume In this study, randomized and in the form of allocation of patients to control and intervention groups after determining the criteria for entering and leaving the study by Blind Randomization software, thus, considering the randomness of the split of the investigator's patients, the effect on the choice The two groups will not control and interact

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical sciences

Street address

Glgasht-Tabriz university of medical science

City

Tabriz

Province

East Azarbaijan

Postal code

516746487

Approval date

2017-12-11, 1396/09/20

Ethics committee reference number

IR.TBZmed.rec.1396.1289

Health conditions studied

1

Description of health condition studied

Idiopathic femoral head Osteonecrosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of the Effect of shoe inserts on Pain Reduction and the Prevention of Clinical and Radiographic Progression in Patients with Idiopathic

femoral head Osteonecrosis.

Timepoint

Every 3 month until one year

Method of measurement

With FICAT and HHS standard forms

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients prescribed for shoe inserts for them. Shoe inserts are used on both feet. shoe inserts are made of silicon and leather with a thickness of one centimeter in the heel area, which gradually decreases to Forefoot. Patients participating in the study are fully justified to use on a day to day basis. It should be noted that their exact presence during the study, in addition to accurate examination of the study, is also useful for the careful follow up of the disease and for the health of patients themselves.

Category

Treatment - Devices

2**Description**

Control group: The control group will only take the usual medical treatment

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz-Shohada hospital

Full name of responsible person

Mahdi pashazadeh

Street address

Golshahr-Elgoli

City

Tabriz

Province

East Azarbaijan

Postal code

5167846487

Phone

+98 41 3389 3221

Email

Dr.m.pashazadeh.85@gmail.com

Web page address

http://Shohadahosp.tbzmed.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza sadeghpour

Street address

Olshahr-elgoli

City

Tabriz

Province

East Azarbaijan

Postal code

5167846487

Phone

+98 41 3389 3221

Fax

+98 41 3389 3221

Email

Dr.m.pashazadeh.85@gmail.com

Web page address

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

No

Title of funding source

Researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr mahdi pashazadeh

Position

Assistant of orthopedie

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Golshahr-Elgoli

City

Tabriz

Province

East Azarbaijan

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Email

Dr.m.pashazadeh.85@gmail.com

Web page address

<http://shohadahosp.tbzmed.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Alireza Sadegpour

Position

Professor of orthopedic

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Golshahr-elgoli

City

Tabriz

Province

East Azarbaijan

Postal code

5167846487

Phone

+98 38 93221

Fax

+98 41 3389 3221

Email

Dr.m.pashazadeh.85@gmail.com

Web page address

<http://shohadahosp.tbzmed.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr mahdi pashazadeh

Position

Assistant of orthopedi

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Golshar-elgoli

City

Tabriz

Province

East Azarbaijan

Postal code

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Phone

+98 41 3389 3221

Fax

+98 41 3389 3221

Email

Dr.m.pashazadeh.85@gmail.com

Web page address

<http://Shohadahosp.tbzmed.ac.ir>

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

Because of the obligation to hide patient information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The study will be published in the form of an article

When the data will become available and for how long

After thesis defense and publication of the article

To whom data/document is available

Everybody's that journal allows

Under which criteria data/document could be used

Help to other researchers and patients

From where data/document is obtainable

The journal and researchers

What processes are involved for a request to access data/document

Journal editor and researchers

Comments