

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation the effects of the local low-power laser therapy on clinical and imaging alterations in patients with avascular necrosis of femoral head

Protocol summary

Study aim

Therapeutic affects Low Power Laser on distraction of this part of bone due to AVN of Femoral Head

Design

This is an interventional quasi-experimental study whit simple randomized method. 32 patients undergo laser therapy.

Settings and conduct

This study will be carried out at Firoozgar Hospital in Tehran. The laser is transmitted through the skin of the hip joint anatomical area during the 9 courses (while each course consists of 10 sessions). This research does not require blinding.

Participants/Inclusion and exclusion criteria

Participants that fall within categories 1 and 2 of the ASA are admitted to the study. They are patients of both sexes, diagnosed with AVN of femoral head (grade 4- 3) and range from 40 to 18 years old. Exclusion criteria: Contraindication for using a laser

Intervention groups

The therapeutic laser characteristics includes: Two types of red (200 MW) and IR (300 MW) lasers transmit through the skin on the anatomical site of the hip joint. The maximum fluence (energy) is 30 J/cm² on 15 points for each joint.

Main outcome variables

Visual Analogue Scale, Range of Motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180305038955N1**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**

Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Aliakbar Jafarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1612

Email address

aajafari41@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of the local low-power laser therapy on clinical and imaging alterations in patients with avascular necrosis of femoral head

Public title

Evaluation the influence of the local low-power laser therapy in patients with avascular necrosis of femoral head

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients from both sexes were entered into the study with grade 1 and 2 on the basis of the American Society of Anesthesiology criteria. The participants were diagnosed as avascular necrosis of femoral head (grade 3-4) based on the diagnostic criteria of the Massachusetts hospital. Age range 18-40 years

Exclusion criteria:

Patients who tend to have surgery Grade 1,2 ,5 and 6 of American Society of Anesthesiologists (ASA) Radiologic Criteria for Femoral head AVN patients were not intended to be treated Malignancy in the vicinity of the treatment area Dermatologic problems which makes the treatment impossible Other invasive or Non-invasive treatments on the affected area

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.IUMS.REC 1396.31422

Health conditions studied**1****Description of health condition studied**

Avascular Necrosis of Femoral Head

ICD-10 code

M87.159

ICD-10 code description

Osteonecrosis due to drugs, unspecified femur

Primary outcomes**1****Description**

Pain

Timepoint

Measure of pain at the beginning of the study (before the intervention) and after each 10-session of treatment period

Method of measurement

Visual Analogue scale (VAS)

2**Description**

Hip motion range

Timepoint

Measure of pain at the beginning of the study (before the intervention) and after each 10-session of treatment period

Method of measurement

Range of Motion

Secondary outcomes

empty

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

In this study, the laser fluence (energy) is transmitted through the skin to the anatomical location of the affected hip (15 points for each joint). The periods of radiations include 9 courses (each course consists of 10 sessions) and a total of 90 sessions over a period of 9 months. The Selected points are those which is recommended in guidelines for acupuncture procedures to control hip pain. The recommended lasers are RED (200 mw) and IR (300 mw) and the maximum fluence (energy) is 30 joules per centimeter squared (30 J/cm²). The laser therapy schedules in each period are ten sessions every two days with a week interval and then the next period will start again

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Aliakbar Jafariyan

Street address

Firoozgar Hospital, Behafarin Avenue

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 8214 1612

Email

aajafari41@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malakooti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 5503

Email

research@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

Aliakbar Jafariyan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Firoozgar Hospital, Behafarin Avenue

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 8214 1612

Email

aajafari41@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Aliakbar Jafariyan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Firoozgar Hospital, Behafarin Avenue

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 8214 1612

Email

aajafari41@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Aliakbar Jafarian

Position

Assistant professor

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Street address

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Province

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Postal code

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Email

aajafari41@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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