Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of local low power laser in the treatment of avascular necrosis of Pediatric’s femoral head

Protocol summary

Study aim
Reducing costs - preserving the health of patients - using a low-complication alternative method for the complicated operation of replacing the femoral head in children with avascular necrosis of the femoral head

Design
Clinical trial without control group, phase 3 on 32 patients.

Settings and conduct
Patients under 18 years of age who refer to the pain clinic in Firouzgar- Hazrat Rasool (PBUH) training center with a diagnosis of Avascular necrosis of femoral head who do not want to undergo surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- no underlying diseases or mild disease under control (ASA1,2) of both sexes with a diagnosis of Avascular necrosis of femoral head grade 4-6 (according to the diagnostic criteria of Massachusetts Hospital 2) including 16 patients with unilateral diagnosis This complication and 16 patients with bilateral diagnosis of this complication 2- Age range 8-15 years 3- Weight within normal range (BMI for men in the range of 22-26 and women in the range of 22-24) 4- Non-agreement to joint replacement surgery; Exclusion criteria include: 1- patient's lack of consent to participate or continue the plan 2- history of cancer 3- sensitivity to laser light

Intervention groups
In this study, separate Red, IR laser through the skin on the anatomical site of the affected hip joint with a determined dose during 6 periods of 16 sessions in total 96 sessions with an amount of 30 joules from the two mentioned lasers for 12 points for each joint in each session - during It is irradiated for 15 months. It should be noted that for patients with bilateral complications, this procedure is performed for the other affected joint with the same method. The treatment course is done for each patient

Main outcome variables
Reducing inflammation - tissue regeneration and revascularization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111121008146N41**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date
2022-11-02, 1401/08/11

Registrant information

Name
Mohammadreza Razaghi

Name of organization / entity
Laser application in medical sciences research center

Country
Iran (Islamic Republic of)

Phone
+98 21 2271 8021

Email address
laser.cntr@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of local low power laser in the treatment of avascular necrosis of Pediatric's femoral head

Public title
Investigating the effect of low-power laser in the treatment of necrosis of the femoral head, a debilitating disease in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
No underlying diseases or mild disease under control (ASA1,2) of both genders with a diagnosis of Avascular necrosis of femoral head grade 4-6 (according to the diagnostic criteria of Massachusetts Hospital Age range 8-15 Weight in the normal range (BMI for men in the range of 22-26 and for women in the range of 22-24) disagree to hip replacement surgery
Exclusion criteria:
Failure of the patient to agree to participate or continue the plan History of cancer Sensitivity to laser light

Age
From **8 years** old to **15 years** old

Gender
Both

Phase
3

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
Organizational committee of ethics in biomedical research of research assistant
Street address
Tehran Province, Tehran, Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave
City
tehran
Province
Tehran
Postal code
1985717443

Approval date
2022-06-26, 1401/04/05

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.185

Health conditions studied

1

Description of health condition studied
Avascular necrosis of femoral head

ICD-10 code
M87.0

ICD-10 code description
Idiopathic aseptic necrosis of bone

Primary outcomes

1

Description
Reducing inflammation - tissue regeneration and revascularization

Timepoint
Red, IR laser separately through the skin on the anatomical site of the affected hip joint with a determined dose during 6 periods of 16 sessions (each period is two months and a ten-day break between each period) (a total of 96 sessions with an amount of 30 joules from the two mentioned lasers) irradiated for 12 points for each joint in each session - during 15 months

Method of measurement
Clinical criteria - MRI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use of Red, IR laser for patients

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
To the pain clinic in Firouzgar - Hazrat Rasool (PBUH)

training center

Full name of responsible person
Ali Akbar Jafarian

Street address
Hazrat Rasool medical center, Mazyar Mansouri st,Starkhan Ave.ttar Khan

City
Tehran

Province
Tehran

Postal code
14456 13131

Phone
+98 21 6435 1000

Email
aajafari41@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi, Vice-Chancellor of Research Affairs

Street address
Shahid Beheshti University of medical sciences, Yaman st, Daneshjoo Blvd

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2271 8021

Email
laser.cntr@sbmu.ac.ir

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
ali akbar jafarian

Position
Assistant Professor of Shahid Beheshti University of Medical Sciences

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Shohada Tajrish Hospital, Shahrdary st, Tajrish sq, Tehran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2271 8021

Email
aajafari41@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
ali akbar jafarian

Position
Assistant Professor of Shahid Beheshti University of Medical Sciences

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Shohada Tajrish Hospital, Shahrdary st, Tajrish sq, Tehran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2271 8021

Email
aajafari41@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
ali akbar jafarian

Position
Assistant Professor of Iran University of Medical

Sciences

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Hazrat Rasool medical center, Mazyar Mansouri street,Satarkhan Ave,Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8021

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