

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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

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Iran (Islamic Republic of)

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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

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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

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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

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Shahid Beheshti University of medical sciences,
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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

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

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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