

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the Effect of Monthly Intravenous Pamidronate in the Treatment of Legg Calve Perthes in Children

Protocol summary

Study aim

Determining the effect of monthly pamidronate intravenous injection in addition to routine treatment in the treatment of children's LCP

Design

This research is a double-blind clinical trial with parallel groups using the random block method and sampling will be done by the available method among LCP patients in two intervention and control groups, and the sample size will be 30 people in each group. Was. The case group will receive pamidronate in addition to routine treatment. The Control group patients will receive routine treatment.

Settings and conduct

This study will be conducted on 60 patients with LCP referred to Mofid Hospital in 1402 and 1403. Patients will be randomly divided into two groups of 30 people. In the case group, pamidronate will be injected monthly and intravenously at 1 mg/kg/dose, and the control group will only receive routine treatment. Both groups will be the same in terms of the type of routine treatment received, the number of visits and other follow-up parameters. Before starting the study, imaging will be done for all patients to assess the condition of the femur bone. Also, this imaging will be repeated six months and one year later. Then, imaging findings, disease grade based on expert opinion and response to treatment will be compared between two groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study will be patients with LCPD and having consent to participate in the study. Exclusion criteria will be receiving previous treatment and receiving other similar drugs.

Intervention groups

Patients in the control group will receive routine treatment of the underlying disease. In addition to routine treatment, patients in the case group, will also receive pamidronate injections.

Main outcome variables

Disease grade, Response to treatment, Clinical signs, Imaging findings.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230526058299N1**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Niloufar Shashaani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

shashaaniniloofar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Monthly Intravenous Pamidronate in the Treatment of Legg Calve Perthes in Children

Public title

The effect of Pamidronate Injection in the Treatment of LCP Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with LCPD Consent to participate in the study

Exclusion criteria:

Received previous treatments receiving other similar drugs

Age

To 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Among the 60 samples that meet the conditions for entering the study, people will be randomly divided into two groups, case and control, using the random block method. Using a calculator, random numbers from 1 to 60 will be generated, 30 numbers and the first number generated by the calculator will be assigned to the case group and the next 30 numbers will be assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the statistical analyzer, a code will be assigned to the patients of each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Student Blvd., Valenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.SBMU.MSP.REC.1402.042

Health conditions studied

1

Description of health condition studied

Legg-Calve'-Perthes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Disease Grade

Timepoint

Referral time, six months and one year after the intervention

Method of measurement

Imaging findings and physical examination

2

Description

Response to treatment

Timepoint

Referral time, six months and one year after the intervention

Method of measurement

Imaging findings and physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine treatment, the group will receive pamidronate for 6 months. A 90 gram ampoule with a dose of 1 mg/kg will be injected every month. The drug will be prepared from Aburihan company and contains disodium pamidronate.

Category

Treatment - Drugs

2

Description

Control group: A group that will only receive routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital Rheumatology Clinic

Full name of responsible person

Reza Shiari

Street address

Mofid Children's Hospital, Shariati Ave, Tehran

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shiareza@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Volenjek Ave., Shahid Beheshti University of Medical Sciences, Tehran, Iran

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1985717443

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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

Niloofar Shashaani

Position

Rheumatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Rhematology

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Latest degree

Medical doctor

Other areas of specialty/work

Rheumatology

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

Rhematology

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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

Demographic information and clinical trial results

When the data will become available and for how long

Access starts one year after results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Research on a related issue

From where data/document is obtainable

Niloofer Shashaani

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

Communicating with the responsible person by email

Comments