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
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Iran (Islamic Republic of)
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+98 21 2222 7021
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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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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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info@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
Niloofar Shashaani
Position
Rheumatology resident
Latest degree
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Other areas of specialty/work
Rhematology
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Person responsible for updating data

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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
Niloofar Shashaani

What processes are involved for a request to access data/document
Communicating with the responsible person by email

Comments