Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 8 weeks versus 12 weeks steroid therapy on serum 25-hydroxy vitamin D level in children with nephrotic syndrome during remission phase: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the efficacy of 8 weeks versus 12 weeks steroid therapy on serum 25-hydroxy vitamin D level in children with nephrotic syndrome during remission phase Design: A randomized clinical trial. Setting and conduct: All eligible patients with nephrotic syndrome who will refer to clinic of pediatrics during the study period will be enrolled in to the trial. Inclusion criteria: (a) age of 1-18 years; (b) affected with nephrotic syndrome; (c) being in remission phase. Exclusion criteria: (a) children with malnutrition; (b) receiving vitamin D supplement during the last three months; (c) having liver, pancreatic, or gastrointestinal diseases; (d) using phenytoin, phenobarbital, isoniazid, or rifampin. Intervention: oral prednisolone 60 mg/square meter daily for 6 weeks and then oral prednisolone 40 mg/square meter every other day for 6 weeks (totally 12 weeks). Control: oral prednisolone 60 mg/square meter daily for 4 weeks and then oral prednisolone 40 mg/square meter every other day for 4 weeks (totally 8 weeks). Primary outcome: measuring the serum 25-hydroxy vitamin D level at the end of treatment through taking blood sample. Secondary outcome: measuring the relapse of nephrotic syndrome at the end of treatment through taking urine sample and measuring proteinuria equal to or greater than 2 plus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404269014N33**
Registration date: **2014-05-03, 1393/02/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks versus 12 weeks steroid therapy on serum 25-hydroxy vitamin D level in children with nephrotic syndrome during remission phase: a randomized clinical trial

Public title

The effect of 8 weeks versus 12 weeks steroid therapy on serum 25-hydroxy vitamin D level in children with nephrotic syndrome during remission phase

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 1-18 years; (b) affected with nephrotic syndrome; (c) being in remission phase. Exclusion criteria: (a) children with malnutrition; (b) receiving vitamin D supplement during the last three months; (c) having liver, pancreatic, or gastrointestinal diseases; (d) using phenytoin, phenobarbital, isoniazid, or rifampin.

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: patients will be divided into two groups according to the time of admission. One group will receive oral prednisolone for 8 weeks and another group will receive oral prednisolone for 12 weeks. Blinding: since the duration of treatment is different in intervention and control groups, blinding is impossible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2013-12-08, 1392/09/17

Ethics committee reference number
D/P/16/35/9/2932

Health conditions studied

1

Description of health condition studied
Nephrotic syndrome

ICD-10 code
N04

ICD-10 code description
Nephrotic syndrome

Primary outcomes

1

Description
the serum 25-hydroxy vitamin D level

Timepoint
at the end of treatment

Method of measurement
through taking blood sample

Secondary outcomes

1

Description
measuring the relapse of nephrotic syndrome

Timepoint
at the end of treatment

Method of measurement
through taking urine sample and measuring proteinuria equal to or greater than 2 plus

Intervention groups

1

Description
oral prednisolone 60 mg/square meter daily for 6 weeks and then oral prednisolone 40 mg/square meter every other day for 6 weeks (totally 12 weeks).

Category
Treatment - Drugs

2

Description
oral prednisolone 60 mg/square meter daily for 4 weeks and then oral prednisolone 40 mg/square meter every other day for 4 weeks (totally 8 weeks).

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beasat Hospital
Full name of responsible person
Dr Aminosadat Sharif
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Beasat Hospital, Shahed Square, Behesh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty