

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 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

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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 Aminasadat Sharif

**Street address**

Beasat Hospital, Shahed Square, Behesh Ave.

**City**

Hamadan

#### 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

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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**

Beasat Hospital

**Full name of responsible person**

Dr Aminasadat Sharif

**Position**

Resident of Pediatrics

#### Other areas of specialty/work

**Street address**

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amin.sharif63@yahoo.com

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#### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Beasat Hospital

**Full name of responsible person**

Dr Hossein Emad Momtaz

**Position**

Pediatrician

**Other areas of specialty/work**

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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*