

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of Helicobacter pylori eradication versus no eradication on disease period and treatment response in children with nephrotic syndrome: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of Helicobacter pylori eradication versus no eradication on disease period and treatment response in children with nephrotic syndrome

##### Design

This is a randomized clinical trial, phase II, in which 48 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible children with nephrotic syndrome who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 2 to 14 years; Nephrotic syndrome; Helicobacter pylori positive Exclusion criteria: Glomerulonephritis; Renal failure; High blood pressure; Using antibiotic or antacid in the past month

##### Intervention groups

Intervention group: Corticosteroid tablet 60 mg/m<sup>2</sup> daily for 2 years plus four-drug treatment for 2 weeks with omeprazole capsule 1 mg/kg daily and metronidazole tablet 20 mg/kg daily and ampicillin capsule 50 mg/kg daily and bismuth citrate tablet 480 mg/kg daily for Control group: Corticosteroid tablet 60 mg/m<sup>2</sup> daily for 2 years

##### Main outcome variables

Primary outcome: Assessing the proteinuria

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N268**  
Registration date: **2019-04-11, 1398/01/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

##### Registration date

2019-04-11, 1398/01/22

##### 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

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2020-03-10, 1398/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Helicobacter pylori eradication versus no eradication on disease period and treatment response in children with nephrotic syndrome: a randomized clinical

trial

## Public title

Effect of Helicobacter pylori eradication versus no eradication on disease period and treatment response in children with nephrotic syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 2 to 14 years; Nephrotic syndrome; Helicobacter pylori positive

### Exclusion criteria:

Glomerulonephritis; Renal failure; High blood pressure; Using antibiotic or antacid in the past month

## Age

From **2 years** old to **14 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

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

Fahmideh Ave

## City

Hamadan

## Province

Hamadan

## Postal code

6517838695

## Approval date

2019-03-09, 1397/12/18

## Ethics committee reference number

IR.UMSHA.REC.1397.959

## 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

Assessing the proteinuria

#### Timepoint

At the end of the first, second and third months

#### Method of measurement

Through the laboratory test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Corticosteroid tablet 60 mg/m<sup>2</sup> daily for 2 years plus four-drug treatment for 2 weeks with omeprazole capsule 1 mg/kg daily and metronidazole tablet 20 mg/kg daily and ampicillin capsule 50 mg/kg daily and bismuth citrate tablet 480 mg/kg daily for

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Corticosteroid tablet 60 mg/m<sup>2</sup> daily for 2 years

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Besat Hospital in Hamadan City

**Full name of responsible person**

Dr. Danyal Isapour

**Street address**

Besat Hospital, Shahed Square

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3364 0030

**Email**

danyal-isapour@yahoo.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

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**Province**

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**Phone**

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**Email**

info.research@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Danyal Isapour

**Position**

Resident of Pediatric

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Besat Hospital, Shahed Square

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Hasan Bazmamoun

**Position**

Podiatrist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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### Person responsible for updating data

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

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Medical Sciences, Shahid Fahmideh Ave

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**Email**

poorolajal@umsha.ac.ir

**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