

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/m² 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/m² 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/m² 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/m² 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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

danyal-isapour@yahoo.com

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

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

hbazmamoun@yahoo.com

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

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

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