

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of specific diet in treatment of patients with persistent microscopic hematuria

Protocol summary

Study aim

Effect of specific diet in treatment of patients with persistent microscopic hematuria

Design

All patients from 6 months to 16 years of age who are referred to the nephrology clinic with diagnosis of isolated asymptomatic microscopic hematuria without a specific cause and any treatment will be enrolled in this study. Patients will be divided into two groups. We will start hypoallergenic diet in group I (study group), and no diet in group II (control group) (usually these patients with asymptomatic microscopic hematuria will be followed with no treatment). Urinalysis for evaluation of RBC number will be evaluated after a while in both groups. (In this study we do not have any intervention in control group, and just follow them in usual situation).

Settings and conduct

Assessment of a child with hematuria is performed at Mofid hospital with a detailed history, physical examination, and simple urine analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 6 months to 16 years with isolated microscopic hematuria without a definite stable cause. Exclusion criteria: Patients with upper urinary tract disease (including glomerular diseases such as IgA nephropathy, thin basal membrane disease, Alport syndrome, post-infection glomerulonephritis, nephropathy membranous), uremic hemolytic syndrome, sickle cell disease, and interstitial disease like pyelonephritis, interstitial nephritis, Papillary necrosis and acute tubular necrosis and vascular diseases and anatomical causes such as hydronephrosis, cystic kidney disease, tumor and trauma). Factitious hematuria.

Intervention groups

Assessment of patients is done by taking a history and urinalysis. The patients will be divided into two groups. The first group is on a hypoallergenic diet and the second group (control group) will receive no intervention. We have no drug intervention in this study.

Main outcome variables

urinary RBC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191230045940N1**

Registration date: **2020-10-07, 1399/07/16**

Registration timing: **retrospective**

Last update: **2020-10-07, 1399/07/16**

Update count: **0**

Registration date

2020-10-07, 1399/07/16

Registrant information

Name

Masoumeh Mohkam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 9658

Email address

mohkam@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2019-03-06, 1397/12/15

Trial completion date

2019-03-06, 1397/12/15

Scientific title

Effect of specific diet in treatment of patients with persistent microscopic hematuria

Public title

Specific diet and hematuria

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Isolated microscopic hematuria without a known cause
Age 6 months to 16 years

Exclusion criteria:

Possibility of upper urinary tract diseases (including glomerular diseases such as IgA Nephropathy, Thoracic Disease, Alport Syndrome, Post-infection Glomerulonephritis, Membrane Nephropathy) Patients infected with uremic hemolytic syndrome and sickle cell disease Multiple Systemic Diseases (such as Lupus, Henoch Schwein Line Purpura, Wegener, Nodosa Polyurethritis, Goodpasture) Interstitial diseases (such as pyelonephritis, interstitial nephritis, papillary necrosis and acute tubular necrosis and vascular diseases and anatomical causes such as hydronephrosis, cystic kidney and tumor diseases and trauma) Inflammations of the lower urinary tract such as (cystitis, urethritis, stones), coagulopathy, tumor, infection, and fabricated hematuria factitious hematuria

Age

From **2 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **122**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 faculty of medicine

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Shariati Avnue

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Postal code

15468-15514

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.SBMU.MSP.REC.1398.046

Health conditions studied**1****Description of health condition studied**

Bloody urine

ICD-10 code

N02

ICD-10 code description

Recurrent and persistent hematuria

Primary outcomes**1****Description**

Number of urine red blood cells

Timepoint

At first (before intervention) and 1month after diet

Method of measurement

Urine analysis

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention 1 group: Intervention as non-allergen food (hypoallergenic Diet) on Patients with asymptomatic microscopic hematuria without any kind of treatment. (Special hypoallergenic diet: omit Salty snack, Chocolates, Fast foods, Industrial beverages and Spicy food from child's diet for 4 weeks).

Category

Treatment - Other

2**Description**

Control group: Intervention 2 group (control group):

Patients with asymptomatic microscopic hematuria without any kind of diet or treatment, they just should be followed. (Usually pediatric patients with asymptomatic microscopic hematuria do not receive any medication or diet and just are followed).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid children's hospital- pediatric nephrology clinic

Full name of responsible person

Masoumeh Mohkam

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Mofid children's hospital, Shariati Ave. Tehran- Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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

Masoumeh Mohkam

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

This is a localized study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available