

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Iranian Traditional Medicine-based diet compared to classical Medicine-based diet on proteinuria in children with nephrotic syndrome. A randomized clinical trial

Protocol summary

Study aim

Primary purpose: evaluation of the effectiveness of classical medicine diet with Iranian medicine approach in comparison with classical medicine diet alone on urinary protein excretion

Design

A clinical trial with the control group, with parallel, randomized groups, on 20 patients. RAS software was used for randomization.

Settings and conduct

The sampling place is Mofid Children's Hospital. Easy random sampling. The patient and the statistician are blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age 2 to 12 years old; diagnosis of nephrotic syndrome; BMI percentile for ages between 5 and 85; CKD1-2; ability and willingness to cooperate in research projects. Exclusion criteria: any severe congenital and inherited disease; heart failure; advanced renal failure; hypo and hyperthyroidism; severe inflammatory diseases such as lupus; diabetes

Intervention groups

In the control group, only classical nutrition (accurate calculation of energy and protein, and restriction of sodium and saturated and trans fats) and in the intervention group, in addition to the classical medicine diet, the recommendations of Iranian Traditional Medicine (ITM) will be given. Dietary interventions in ITM for nephrotic syndrome include paste, pomegranate paste, and wheat bran. The diet of the control group is adjusted based on traditional medicine interventions so that there is no difference in terms of energy and macronutrients.

Main outcome variables

Random urine protein; lipid profile; serum Album

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047027N2**

Registration date: **2021-11-08, 1400/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**

Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

alireza rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7736 4020

Email address

a74.rahmani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Iranian Traditional Medicine-based diet compared to classical Medicine-based diet on proteinuria in children with nephrotic syndrome. A randomized clinical trial

Public title

Traditional medicine diet in nephrotic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 2 and 12 years old
Diagnosis of nephrotic syndrome
Body mass index (BMI) 5 to 85th percentile
Chronic kidney disease stage 1-2 (CKD 1-2)
Ability and willingness to collaborate on research projects

Exclusion criteria:

Any severe congenital or inherited diseases
Heart failure
Advanced renal failure
Hypo and hyperthyroidism
Severe inflammatory diseases such as lupus
Diabetes mellitus

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly divided into two groups of 10, using the RAS software, and studied for one month. A statistician will do this process.

Blinding (investigator's opinion)

Single blinded

Blinding description

During the visit for each patient in the control group, a diet based on classical medicine is calculated for them and explained to them along with an attached sheet. In addition to receiving the classical medicine diet, patients in the intervention group also receive Iranian traditional medicine food interventions. Since patients were visited separately and did not communicate with each other, they would not be aware of the different regimens prescribed by the researcher and would be blind to the intervention. In addition, the statistician in charge of data analysis does not know the control and intervention group and is blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahed University

Street address

Shahed University, in front of the Holy Shrine of Imam Khomeini, The beginning of the Tehran-Qom freeway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2021-09-06, 1400/06/15

Ethics committee reference number

IR.SHAHED.REC.1400.064

Health conditions studied

1

Description of health condition studied

Nephrotic Syndrome

ICD-10 code

N03

ICD-10 code description

A Chronic nephritic syndrome with C3 glomerulonephritis

Primary outcomes

1

Description

Random urine protein

Timepoint

Start of study and end of study (after 4 weeks)

Method of measurement

Urine analysis methods for random urine protein

2

Description

Lipid profiles

Timepoint

Start of study and end of study (after 4 weeks)

Method of measurement

Biochemical methods for lipid profiles

3

Description

Albumin serum

Timepoint

Start of study and end of study (after 4 weeks)

Method of measurement

Biochemical methods for albumin serum

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: quince sauce (1 tablespoon after meals), pomegranate paste (1 tablespoon before meals), and ground barley (Savigh) (1 tablespoon per day)

Category

Treatment - Other

2

Description

Control group: classical medicine diet (accurate calculation of energy and protein, sodium and saturated and trans fats)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Reza Ilkhani

Street address

Mofid Children's Hospital, Shariati St.

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Sponsors / Funding sources

1

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Grant name

Shahed University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

Reza Ilkhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The protocol of how the work is performed and the results are shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Faculty members of nutrition and traditional medicine

From where data/document is obtainable

Via message to the first author's personal email.

What processes are involved for a request to access data/document

Message to email. Information will be sent if needed.

Comments