

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of vitamin E intake in improving the symptoms of children 2 to 12 years old with urinary tract infections

Protocol summary

Study aim

Determining the effect of vitamin E intake on improving the symptoms of children 2 to 12 years old with urinary tract infections admitted to Ayatollah Mousavi Hospital in 2021-2022

Design

Clinical trial with control group, with parallel, randomized, phase 3 groups on 48 patients

Settings and conduct

This study is performed as a clinical trial for 48 patients aged 2-12 years who will be admitted to the pediatric ward of Ayatollah Mousavi Hospital in Zanjan in 2021-2022 due to urinary tract infection as indicated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete consent to participate in the study, all patients 2 to 12 years with a diagnosis of urinary tract infection Exclusion criteria: emphysematous pyelonephritis, renal abnormalities, vitamin E sensitivity or intolerance

Intervention groups

An intervention group and a control group participated in this study. In the intervention group, in addition to routine treatments, vitamin E capsules will be taken orally dose 100 units daily for 10 days, and in the control group will receive only routine treatments.

Main outcome variables

Improve the symptoms of urinary tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210627051722N1**

Registration date: **2021-07-14, 1400/04/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-14, 1400/04/23**

Update count: **0**

Registration date

2021-07-14, 1400/04/23

Registrant information

Name

Malihe naghdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0000

Email address

drmnaghdi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin E intake in improving the symptoms of children 2 to 12 years old with urinary tract infections

Public title

Evaluation of the effect of vitamin E intake in improving the symptoms of children 2 to 12 years old with urinary tract infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study All patients 2 to 12 years with diagnosis of urinary tract infection (urine analysis and positive urine culture)

Exclusion criteria:

Emphysematous pyelonephritis Renal anomalies Allergy to vitamin E or intolerance to it

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected from 48 patients aged 2 to 12 years with a diagnosis of urinary tract infection admitted to the pediatric ward in Ayatollah Mousavi Hospital, Zanjan University of Medical Sciences. Individuals are randomly divided into two groups receiving vitamin E and the control group. Random allocation will be considered as Block permutation Randomization with four blocks including AABB-BBAA-BABA-ABAB-BAAB-ABBA and individuals will be assigned to intervention or control groups based on these blocks (which will be randomly selected).

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 Deputy of Research and Technology of Zanjan University of Medical Sciences

Street address

Deputy of Research and Technology, third floor, Second building, Central Headquarters of Zanjan University of Medical Sciences, The beginning of Jomhuri Eslami Boulevard, Azadi Blv, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.ZUMS.REC.1398.448

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

urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

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

Improve the symptoms of urinary tract infection

Timepoint

On days 4 and 10 of treatment

Method of measurement

Urine culture

Secondary outcomes

empty

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

Intervention group: In the intervention group, in addition to routine treatments, vitamin E capsules are taken orally in 100 units daily for 10 days.

Category

Treatment - Drugs

2**Description**

Control group: In the control group will receive only routine treatments.

Category

N/A

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

Ayatollah Mousavi Hospital

Full name of responsible person

Dr. Farzaneh Moezzi

Street address

Ayatollah Mousavi Hospital, Gavazang Street, Soboti

Blv, Zanjan, Iran

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4513956183

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Email

Mousavihospital@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mazyar Payda

Street address

Vice chancellor for research, Zanjan University of Medical Sciences, Azadi Blvd. Zanjan

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Research@zums.ac.ir

Web page address

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Farzaneh Moezzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Farzaneh Moezzi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Maliheh Naghdi

Position

Pediatric specialist student

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Web page address

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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

After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).

When the data will become available and for how long

The start of the access period to the data of this study will be from Early 2022 and approximately 6 months after the publication of the results.

To whom data/document is available

The data from this study will be available to all people who can play a role in caring for children with urinary tract infection in 2 to 12 years, such as families, and healthcare workers.

Under which criteria data/document could be used

The researcher tend to use data to improve patients, especially children with urinary tract infection in 2 to 12 years.

From where data/document is obtainable

To receive information anyone can be use the following email:moezi@zums.ac.ir

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

The data will be sended to the applicants after her introduction and the reason for the need for data

Comments