Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Ayatolllah Mousavi Hospital, Gavazang Street, Soboti

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Mousavihospital@zums.ac.ir
Web page address
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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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Email
Research@zums.ac.ir
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=3
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
Street address
Ayatollah Mousavi Hospital, Gavazang Street,Pro. Soboti Blv, Zanjan, Iran
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Person responsible for scientific inquiries

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Position
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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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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