

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effect of vitamin c on recurrent urinary tract infection in children

Protocol summary

Study aim

Evaluation of effect of vitamin C on recurrent urinary tract infection in children

Design

The present study is a clinical trial with a control group, with parallel groups, randomized (using block randomization), phase 3 on 120 patients.

Settings and conduct

In this randomization clinical trial, children with urinary infection who have referred to Amirkabir Arak Hospital with symptoms of urinary infection and positive urine culture will be divided into two equal intervention and control groups by means of block randomization. In the intervention group, children were given 250 mg of chewable vitamin C daily in addition to the classical treatment of urinary tract infection for one month. While in the control group, they only receive the classical treatment of urinary infection. Finally, two groups will be evaluated in terms of study results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children with urinary tract infections who have been referred to Amirkabir Arak Hospital with symptoms of urinary tract infection and their infection has been proven by urine culture; Age 2-18 years; The presence of the same urine germs in the urine culture
Exclusion criteria: history of constipation; recent use of vitamin C; history of kidney stones; Prohibition of vitamin C consumption in the patient

Intervention groups

In the intervention group, along with the classical treatment of urinary infection, vitamin C with a dose of 250 mg chewable is given daily for one month. In the control group, only the classical treatment will be received, and after one month, a urine culture will be taken.

Main outcome variables

The result of urine culture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N19**

Registration date: **2023-11-22, 1402/09/01**

Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **1**

Registration date

2023-11-22, 1402/09/01

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-29, 1402/09/08

Expected recruitment end date

2024-02-27, 1402/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of vitamin c on recurrent urinary tract infection in children	
Public title	The effect of vitamin C on the recurrence of urinary tract infection in children
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Children with urinary infection who have referred to Amirkabir Arak hospital with symptoms of urinary infection and their infection has been proven by urine culture. Age 2-18 years The presence of the same microorganism in urine culture
Exclusion criteria:	History of constipation Recent use of vitamin C History of kidney stones Prohibition of vitamin C consumption in patients
Age	From 2 years old to 18 years old
Gender	Both
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com , blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Arak University of Medical Sciences
Street address	Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City	Arak
Province	Markazi
Postal code	3848176941
Approval date	2023-06-06, 1402/03/16
Ethics committee reference number	IR.ARAKMU.REC.1402.060
Health conditions studied	
<u>1</u>	
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	
<u>1</u>	
Description	Urine culture
Timepoint	One month after the intervention
Method of measurement	Urinalysis
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: For one month, in addition to the classical treatment of urinary infection, vitamin C from Hakiman Teb Kar Pharmaceutical Company is given in a dose of 250 mg chewable daily.
Category	Treatment - Drugs
<u>2</u>	
Description	Control group: only the classical treatment will be

received, and after one month, a urine culture will be taken.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Dr. Manijeh Kohbazi

Street address

Vice Chancellor for Education, Amir Kabir Hospital,
Arak, Iran

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m_kahbazi77@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mehdi Salehi

Street address

Research Assistant, Arak University of Medical
Sciences, Basij Square, Sardasht, Arak, Iran

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Manijeh Kohbazi

Position

Associate 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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Full name of responsible person

Dr. Parsa Yousefi Chaijan

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mitra Shahrjerdi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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 conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2024/04/20 to 2027/04/20 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

Academic researchers and university professors can request the use of data from Dr. Manijeh Kohbazi after contacting the relevant professor by message or email. Dr. Manijeh Kohbazi: Phone: 09181614351 Email: m_kahbazi77@yahoo.com Address: Arak, Amir Kabir Hospital, Hospital Education Vice-Chancellor

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

Letter writing should be done with professors and universities.

Comments