

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of vitamin C supplementation in the treatment of urinary tract infection in children

Protocol summary

Summary

The main purpose of this study is effect of vit C in reduction of UTI complications. There are many complications related to UTI. Because of that, using of some supplements such as Vit C has been recommended for reducing of these complications. Vit C effects on hematopoietic system, urine acidity and growth reducing of gram negative bacteria, main cause of UTI. Until now, there is no complete study about effects of Vit C in UTI complications. This study is a randomized double blind clinical trial study. Within a year; 154 patients with confirmed urinary tract infection (positive culture or clinical signs associated with urine) after obtaining the entry criteria, including girls 3 to 12 years are investigated. Exclusion criteria including out of age 3 to 12 years old and renal anomalies. The Case group: We prescribe Ceftriaxon 50-75 mg/kg/IV/daily and then oral Cefexime for 14 days. The control group: Conventional therapy and oral vitamin C 250 mg tablets for 14 days. Clinical symptoms and urine culture after the first 48 hours and 10 days after treatment will be checked in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110307942N1**

Registration date: **2012-04-17, 1391/01/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-17, 1391/01/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences and Health Services -
Department of Education - Dr. Ashtiani

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin C supplementation in the treatment
of urinary tract infection in children

Public title

The effect of vitamin C supplement in the treatment of
urinary tract infection in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All of girls who are between age 3 to 12
that diagnosed as an urinary infection by pediatrician are
eligible to enter to study. Exclusion criteria: The girls who
are less than 3 years and more than 12 years ; All sick
children whose parents disagree to cooperate ; Patients

with renal anomalies ; Patients with kidney stones ;
Positive urine culture with several types of germs ; Any
drug resistant ; Patients who are under other
medications ; history of recurrent urinary tract infection ;
The inappropriate use of other supplements

Age

From **3 years** old to **12 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **154**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak University of Medical Sciences

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3848176941, Pardis educational complex , basij
square , Sardasht , Arak, Arak University of Medical
Sciences-Markazi Province , Iran

City

Arak

Postal code

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Approval date

2011-07-04, 1390/04/13

Ethics committee reference number

90-109-11

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**

fever

Timepoint

Daily; until 14 days

Method of measurement

Clinical questionnaire

2**Description**

Urine culture

Timepoint

48 hours and 10 days after treatment

Method of measurement

Coloni Count

3**Description**

Abdominal pain

Timepoint

Daily; until 14 days

Method of measurement

Clinical questionnaire

4**Description**

Dysuria

Timepoint

Daily; until 14 days

Method of measurement

Clinical questionnaire

5**Description**

Frequent urination

Timepoint

Daily; until 14 days

Method of measurement

Clinical questionnaire

6**Description**

Urinary incontinence

Timepoint

Daily; until 14 days

Method of measurement

Clinical questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: We will prescribe routine medication on UTI including ceftriaxone 50-75mg/kg/daily/iv/q12h for 2 days and following by cefixime 12mg/kg/daily/q12h for 12 days, orally.

Category

Treatment - Drugs

2

Description

"Case control : We will prescribe routine medication for UTI plus Vit C 250 mg/daily for 14 days, orally."

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Yousefi . P. Dr - Goodarzi .A.A.Dr

Street address

Amir Kabir Hospital Education

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

دانشگاه علوم پزشکی اراک

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences and Health Services

Full name of responsible person

Yousefi P . Dr

Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty