

# 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

Ali Ahmad Goodarzi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1278 9047

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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

**Street address**

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

**City**

Arak

**Postal code**

3848176941

**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

**City**

Arak

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ashtiani CH S.PhD

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

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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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The specialty of kidney and urinary

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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*