

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation of the effectiveness of zinc supplementation in children with urinary tract infection

#### Protocol summary

##### Summary

The Urinary Tract Infection is an illness with prominent symptoms of fever, abdominal pain, urgency, dysuria, frequency, dribbling and urinary incontinence. UTI is one of the most common diseases in children. Zinc is an essential trace element. Symptoms attributable to zinc deficiency include growth failure, impaired immunity and resistance to infection. The aim of this study is to evaluate the effectiveness of zinc supplementation in the treatment of children with UTI. This is a randomized clinical trial conducted on 200 children between 3-12 years old( female ) with UTI and without nrogenic bladder, anatomical abnormalities, or any other malformations or kidney stones. Patients were divided into intervention and control groups. Subjects in the intervention group received zinc (1mg/kg/day) supplementation while control group received usual antibiotic treatment without zinc supplementation. Treatment outcomes including lab test, clinical condition and UTI symptoms including fever, dysuria and urinary frequency were compared in the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903094056N1**

Registration date: **2010-06-13, 1389/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-06-13, 1389/03/23

##### Registrant information

##### Name

Zahra Moghadasi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1417 3517

##### Email address

moghadasi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Funded by investigator

##### Expected recruitment start date

2008-04-20, 1387/02/01

##### Expected recruitment end date

2009-05-22, 1388/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of zinc supplementation in children with urinary tract infection

##### Public title

Evaluation of the effectiveness of zinc supplementation in children with urinary tract infection

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Female children 3 to 12 years old with UTI, without nrogenic bladder, anatomical abnormalities, or any other malformations or kidney stones Exclusion criteria: Lack of patient cooperation, inappropriate use of prescribed drugs, history of recurrent UTI, those who have been treated for their UTI with drugs other than Ceftriaxon and Cefoxim

## Age

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

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Arak Medical Science University

##### Street address

Arak University of Medical Sciences

##### City

Arak

##### Postal code

3848176941

#### Approval date

2008-07-21, 1387/04/31

#### Ethics committee reference number

87/40/2

## 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

Urinary Tract Infection

## Timepoint

14 days after treatment (Daily 14 days) - 7 to 10 days after the end of treatment ( Urine Culture)

## Method of measurement

Asking mother and child - Results of urine tests

### 2

#### Description

Dysuria

#### Timepoint

14 days after treatment (Daily 14 days) - 7 to 10 days after the end of treatment ( Urine Culture)

#### Method of measurement

Asking mother and child - Results of urine tests

### 3

#### Description

Abdominal pain

#### Timepoint

14 days after treatment (Daily 14 days) - 7 to 10 days after the end of treatment ( Urine Culture)

#### Method of measurement

Asking mother and child

### 4

#### Description

Fever

#### Timepoint

14 days after treatment (Daily 14 days) - 7 to 10 days after the end of treatment ( Urine Culture)

#### Method of measurement

Asking mother and child - Thermometer

### 5

#### Description

Frequency

#### Timepoint

14 days after treatment (Daily 14 days) - 7 to 10 days after the end of treatment ( Urine Culture)

#### Method of measurement

Asking mother and child - Results of urine tests

## Secondary outcomes

### 1

#### Description

Anorexia

#### Timepoint

14 days after treatment

#### Method of measurement

Mother and child statement

### 2

#### Description

Growth failure

#### Timepoint

6 months after treatment

**Method of measurement**

Mother's remarks

**3****Description**

Weight loss

**Timepoint**

Three month after treatment

**Method of measurement**

Mother's remarks

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

In the case group with zinc sulfate (1mg/kg/day)

**Category**

Treatment - Drugs

**2****Description**

In the control group without zinc supplementation

**Category**

N/A

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

Arak Amirkabir Hospital

**Full name of responsible person**

Dr Parsa Yousefi

**Street address**

Pediatric clinic, Amirkabir Hospital

**City**

Arak

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Saeed Changizi Ashtiyani

**Street address**

Vice chancellor for research

**City**

Arak

**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**

*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

**Full name of responsible person**

Dr Parsa Yousefi

**Position**

Pediatric Nephrologist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University Medical Sciences

**Full name of responsible person**

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**Position**

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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*