

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 norogenic 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 norogenic 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**Pardis Educational Complex, Arak Amirkabir Hospital,
Basij Sq.,**City**

Arak

Postal code

3848176941

Phone

+98 86 1417 3517

Fax**Email**

parsayousefichaijan@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak medical Science University

Full name of responsible person

Dr Parsa Yousefi

Position

Pediatric Nephrologist

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

Pardis Educational Complex, Basij Sq.,

City

Arak

Postal code

3848176941

Phone

+98 86 1417 3517

Fax**Email**

parsayousefichaijan@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University Medical Sciences

Full name of responsible person

Dr Parsa Yousefi

Position

Pediatric Nephrologist

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

Arak Amirkabir Hospital

City

Arak

Postal code

3848176941

Phone

+98 86 1417 3517

Fax**Email**

parsayousefichaijan@yahoo.com

Web page address

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