

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation of zinc supplementation with treatment of children with urinary tract infection

#### Protocol summary

##### Study aim

Evaluation of urine analysis and its normalized in children with urinary infection (Uti) receive zinc(+zinc) and don't receive zinc(-zinc) Comparison of frequency distribution and its negativity in children with uti,(+zinc)and(- zinc) Comparison of zinc supplementation in treatment of children with Uti,(+zinc)and(-zinc) Comparison of zinc supplementation in improve disease symptoms of children with Uti,(+zinc)and(-zinc) Comparison of hospitalization time in children with Uti, (+zinc)and(-zinc)

##### Design

Clinical trial,With parallel groups,Single blind,Unaccidental

##### Settings and conduct

Clinical trial over 3 to 12 years old children affected to clinical urinary infection hospitalized in the Zanjān Ayatollah Mosavi Hospital will be done in 1397. Sample are divided into 2 groups of instance and case. The interference group not only will take urinary infection treatment, but also they will receive 1cc/kg zinc sulfate syrup, but instance group is unaware of being this interference on case group. All the examples will be sent to hospital and results of experiments and stopping symptoms during hospitalization will be collected and analyzed via the questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 3 to 12 years old-Uti persistence  
Exclusion criteria: Change in treatment-Personal satisfaction-Incorrect use of drug

##### Intervention groups

Using 1cc/kg of zinc sulfate syrup for 14 days furthermore than uti treatment

##### Main outcome variables

Zinc, urinary infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181023041439N1**  
Registration date: **2018-12-16, 1397/09/25**  
Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

##### Registration date

2018-12-16, 1397/09/25

##### Registrant information

##### Name

Nahideh Bizhan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3344 0087

##### Email address

2nb1365@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

2018-03-21, 1397/01/01

##### Actual recruitment end date

2018-09-22, 1397/06/31

##### Trial completion date

2018-09-22, 1397/06/31

##### Scientific title

Evaluation of zinc supplementation with treatment of children with urinary tract infection

**Public title**

Evaluation of Zinc in urinary tract infection

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

3 to12 years old Urinary tract infection(Pyelonephritis)

**Exclusion criteria:**

Change in treatment Personal satisfaction Incorrect use of drug

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **52**

Actual sample size reached: **52**

**Randomization (investigator's opinion)**

Not randomized

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

Single blinded

**Blinding description**

Afer a complete description and consciously satisfaction a gruop of childen receive zinc sulfat furthermore Urinary tract infection treatment and childrenen themselves and theirre observant dont khnow that the control group will not get zinc sulfat ,the control group that just recieve urinary tract infection treatment is unaware of extance of interference group they took zinc syrup

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Zanja university of medical Sciences

**Street address**

End of mahdavi street,Shahrak karmandan Blvd.,Zanja Town,

**City**

Zanja

**Province**

Zanja

**Postal code**

94149-74877

**Approval date**

2018-04-26, 1397/02/06

**Ethics committee reference number**

IR.ZUMS.REC.1397.010

**Health conditions studied****1****Description of health condition studied**

Urinary infection

**ICD-10 code**

N39.0

**ICD-10 code description**

Urinary tract infection, site not specified

**Primary outcomes****1****Description**

Percent ofChildrene with urinary tract infection (Positive urine culture)

**Timepoint**

Evaluation of urine culture after48 hour and 14day after bigining of zinc

**Method of measurement**

Urine analysis and urine culture

**Secondary outcomes****1****Description**

"End of fever"

**Timepoint**

"During hospitilization"

**Method of measurement**

"Questionnaire"

**2****Description**

"Dysuria"

**Timepoint**

"During hospitilization"

**Method of measurement**

"Questionnaire"

**3****Description**

"Stomach pain"

**Timepoint**

"During hospitilization"

**Method of measurement**

"Qustonnaire"

#### 4

**Description**

"Duration of hospitalization"

**Timepoint**

"During hospitalization"

**Method of measurement**

"Questionnaire"

### Intervention groups

#### 1

**Description**

"Intervention group": 26 of 3 to 12 years old child from both girl and boy affected to clinical urinary infection hospitalized in the Zanjān Ayatollah Mosavi Hospital in 1397 that have inclusion criteria have fever and urinary and stomach symptoms and positive urine analysis with pyelonephritis that note only will take urinary infection treatment ceftriaxone 50 to 75 mg/kg/day/iv and oral cefixim if necessary, but also they will receive 1cc/kg zinc sulfate syrup of Darupakhsh with density 5mg in 5ml daily for 14 days, at least one hour before or 2 hours after meal. All the examples will be sent to hospital and results of experiments and stopping symptoms during hospitalization will be collected and analyzed via questionnaire.

**Category**

Treatment - Drugs

#### 2

**Description**

"Control group": 26 of 3 to 12 years old from child both girl and boy with UTI that do not receive any intervention for more than UTI treatment

**Category**

N/A

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Zanjān University of Medical Sciences, Mousavi Hospital

**Full name of responsible person**

Nahideh Bizhan

**Street address**

Gavazang Road., Zanjān

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**Province**

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4513956183

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**Email**

Mousavihospital@zums.ac.ir

**Web page address**

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Zanjān University of Medical Sciences

**Full name of responsible person**

Alireza Shoghli

**Street address**

Azadi Blv., Zanjān Town

**City**

Zanjān

**Province**

Zanjān

**Postal code**

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+98 24 3422 4770

**Email**

research@zums.ac.ir1

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjān 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**

Zanjān University of Medical Sciences

**Full name of responsible person**

Nahideh Bizhan

**Position**

Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Fax****Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information"

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available