

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

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Province

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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 Zanjani 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 cefixime 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

Zanjan University of Medical Sciences, Mousavi Hospital

Full name of responsible person

Nahideh Bizhan

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Gavazang Road., Zanjan

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Mousavihospital@zums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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

Zanjan 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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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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