Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Efficacy and Safety of Hydrochlorothiazide as an Adjunct Therapy for Clearing Urinary Tract Infections in Children

Protocol summary

Study aim
Determination of the safety and efficacy of Hydrochlorothiazide as an adjuvant therapy for Pediatric urinary tract infection

Design
A Phase 2, randomized, parallel-group, open-label, controlled clinical trial involving 74 patients, with randomization performed using the Excel rand function.

Settings and conduct
Following the acquisition of informed consent from parents, tests will be performed on patients presenting to the inpatient and outpatient departments of Amirkabir Hospital in Arak and lab results and checklists will be kept confidential. Patients will be randomly assigned using a permutation based method to the intervention or control group and will undergo the intended intervention. Tests will be Repeated ten days after the start of treatment and Lab results and checklist information will be collected confidentially by the study investigator. This study will not involve blinding.

Participants/Inclusion and exclusion criteria
The inclusion criteria for this study are an age range of 1 to 18 years and the presence of a urinary tract infection. Patients with anatomical abnormalities of the urinary system such as labial adhesions, renal dysfunction, neurogenic bladder, or voiding disorders will be excluded from the study.

Intervention groups
Control group: They receive antibiotic therapy as prescribed by the attending pediatrician without hydrochlorothiazide for 7 days. Intervention group: They receive antibiotic therapy as prescribed by the attending pediatrician plus Hydrochlorothiazide 25 mg tablets at a dosage of 0.5 mg/kg administered as a single daily dose (maximum 100 mg/day) for 7 days.

Main outcome variables
Primary outcome: Eradication of urinary tract infection; secondary outcomes: fever, urinary frequency, urinary dribbling, dysuria, urinary urgency, urinary incontinence, abdominal pain, Malaise, irritability, drug safety, and drug efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260723070321N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date
2026-08-01, 1405/05/10

Registrant information

Name
Arshia Khalili

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3223 7510

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arshiakhalili3@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-06, 1405/06/15

Expected recruitment end date
2027-03-06, 1405/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Efficacy and Safety of Hydrochlorothiazide as an Adjunct Therapy for Clearing Urinary Tract Infections in Children

Public title
Effect of Hydrochlorothiazide in Treatment of Urinary Tract Infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All Children Aged 1 to 18 Years With Urinary Tract Infection
Exclusion criteria:
Anatomical Abnormalities of the Urinary System Such as Labial Adhesions Renal Failure Neurogenic Bladder Voiding Dysfunction

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this Randomized Clinical Trial, Participants will be allocated to the Intervention and Control Groups in a 1:1 Ratio using Permuted Block Randomization with a Block Size of Six after Enrollment into the Study. The Unit of Randomization is the Individual Participant. Stratified Randomization will not be used. The Randomization Sequence will be generated Prior to the Initiation of the Study using Statistical Software. Participants will be assigned to the Study Groups According to the Generated Randomization Sequence by the Supervising Investigator. No Specific Allocation Concealment Method will be implemented in this Study.

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
Ethics Committee of Arak University of Medical Sciences
Street address
Payambar-e Azam University Complex, Basij Square, Sardasht Area
City
Arak
Province
Markazi
Postal code
3848176941

Approval date
2026-07-12, 1405/04/21

Ethics committee reference number
IR.ARAKMU.REC.1405.154

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
Eradication of Urinary Tract Infection

Timepoint
Urine Sample Collection 10 Days After Receiving Treatment.

Method of measurement
Microscopic examination and culture of urine sample

Secondary outcomes

1

Description
Improvement of fever after receiving treatment

Timepoint
At the beginning of the study and 10 days after the start of treatment

Method of measurement
A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

2

Description

Improvement of frequent urination after receiving treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

3

Description

Improvement of dribbling after receiving treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

4

Description

Improvement of Dysuria after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

5

Description

Improvement of Urgency after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

6

Description

Improvement of Incontinency after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

7

Description

Improvement of Abdominal pain after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

8

Description

Improvement of Malaise after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

9

Description

Improvement of irritability after receiving Treatment

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

A checklist of urinary tract infection symptoms that assesses presence and duration of the following: Fever, Urinary frequency, Urinary dribbling, Dysuria, Urgency, urinary incontinence, abdominal pain, Malaise and irritability.

10

Description

Assessment of the drug safety of Hydrochlorothiazide in the treatment of Pediatric Urinary Tract Infections.

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

Measurement of Serum Sodium, Potassium, Blood Urea Nitrogen and Creatinine levels via Blood test

11

Description

Evaluation of the Effectiveness of Hydrochlorothiazide on Symptom Improvement and Eradication of Pediatric Urinary Tract Infection

Timepoint

At the beginning of the study and 10 days after the start of treatment

Method of measurement

Microscopic Examination and Culture of Urine Sample and Checklist

Intervention groups

1

Description

Intervention group: Patients receive Antibiotic Therapy as prescribed by the Attending Pediatrician, along with Hydrochlorothiazide (25 mg tablets; manufactured by Aburaihan Pharmaceutical Co., Tehran, Iran) at a dosage of 0.5 mg/kg—administered as a Single daily dose (Maximum 100 mg/day) for 7 days.

Category

Treatment - Drugs

2

Description

Control group: Patient receive Antibiotic therapy for 7 days, as prescribed by the Attending Pediatrician, without Hydrochlorothiazide.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Arshia Khalili
Street address
Parastar Square., Alam-ol-Hoda Ave., Shahid Shirody Blvd., Arak
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Email
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Web page address
https://arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Behzad Khansarinejad
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Parastar Square., Alam-ol-Hoda Ave., Shahid Shirody Blvd., Arak
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Postal code
3819693181
Phone
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Fax
+98 86 3313 2510
Email
amirkabir-hospital@arakmu.ac.ir
Web page address
https://arakmu.ac.ir

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
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
Arak University of Medical Sciences
Full name of responsible person
Arshia Khalili
Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Position
Medical student (Intern)

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The results examined in the study—such as blood and urine test findings and items covered in checklists—will be shareable after the study participants have been de-identified.

When the data will become available and for how long
Data from the study will be available for up to six months after the publication of the results.

To whom data/document is available
Data derived from the study will be available to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used
Researchers affiliated with academic and scientific institutions can utilize the data and results of this study for citation purposes and to conduct further research.

From where data/document is obtainable
To obtain the data and documentation resulting from this study, please contact the project lead via email at arshiakhalili3@gmail.com

What processes are involved for a request to access data/document
The applicant must contact the project executor via email, and the results will be sent within one week. arshiakhalili3@gmail.com

Comments