Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Investigating the effect of dexamethasone injection in the first 24 hours in preventing kidney scaring in children with pyelonephritis

Protocol summary

Study aim

The general aim of the study is to determine the effect of dexamethasone injection in the first 24 hours in preventing scar formation in patients with pyelonephritis.

Design

In this randomized, prospective, double-blind clinical trial study, children will be placed according to the row of the list in such a way that children with even rows will be placed in group A and children with odd rows will be placed in group B. Basically, double blocks (AB) will be formed.

Settings and conduct

This study will be conducted in the children's department of Sanandaj Mission Hospital in children aged 1 to 12 years with proven acute pyelonephritis (APN) in both groups A and B. In group A, in addition to routine care, a 3-day course of intravenous corticosteroids (dexamethasone 0.30 mg/kg/day) twice a day, and group B will not receive any medication other than routine care.

Participants/Inclusion and exclusion criteria

The inclusion criteria include children aged 1 month to 12 years with the first episode of fever T > 38°C and having a urinary tract infection and a positive urine culture, the presence of a positive urine culture, which according to the definition includes at least 10000 CFUs/mL from a clean sample obtained with a urine bag. or at least 10000 CFUs/mL from the sample obtained by catheterization or the growth of any amount of bacteria from the sample obtained by suprapubic aspiration. Exclusion criteria included endocrine disease, known immunosuppressive therapy, cancer or uropathy, and those who had an abnormal DMSA before late assessment (at least 6 months follow-up) and had a second UTI.

Intervention groups

Study participants in group A will receive dexamethasone (0.15 mg/kg per dose every 12 hours for 4 days) in addition to usual care, and group B will receive only usual care.

Main outcome variables

Scar formation; Possible side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231226060526N1**
Registration date: **2024-02-13, 1402/11/24**
Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**
Update count: **0**

Registration date

2024-02-13, 1402/11/24

Registrant information

Name

Syed Zia Hejazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 87 3361 8356

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of dexamethasone injection in the first 24 hours in preventing kidney scaring in children with pyelonephritis

Public title
Investigating the effect of dexamethasone injection in the first 24 hours in preventing kidney scaring in children with pyelonephritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children from 1 month to 12 years with first episode of fever T > 38°C having a urinary tract infection and a positive urine culture The presence of a positive urine culture, which according to the definition includes at least 100000 CFUs/mL from a clean sample obtained with a urine bag, or at least 10000 CFUs/mL from a sample obtained by catheterization, or the growth of any amount of bacteria from a sample obtained by suprapubic aspiration.

Exclusion criteria:
Endocrine disease Immunosuppressive therapy Known cancer or uropathy Those who had an abnormal DMSA before late assessment (at least 6 months follow-up) had a second UTI.

Age
From **1 year** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample size was calculated based on the study of Liviana Da Dalt et al., which had 42 people in each group and assumed a 20% difference in scar formation in the two groups (in other words, a 20% reduction in scar formation in the group receiving dexamethasone) and with the following assumptions: 49 people were obtained in each group, and to increase the accuracy of the study, 50 people in each group and a total of 100 people are included in this study. Children according to the row of the list in such a way that children with even rows will be placed in group A and children with odd rows will be placed in group B. Double blocks (AB) will be formed.

Blinding (investigator's opinion)
Double blinded

Blinding description
After the grouping, the patient care team will inject drugs and placebos to the patients of the designated groups according to the instructions, and the researcher and the patient will not be informed about the status of the grouping and the type of drug prescribed in the group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran Street

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Sanandaj

Province
Kurdistan

Postal code
6618634683

Approval date
2023-08-22, 1402/05/31

Ethics committee reference number
IR.MUK.REC.1402.161

Health conditions studied

1

Description of health condition studied
Acute pyelonephritis

ICD-10 code
N13.7

ICD-10 code description
Vesicoureteral-reflux

Primary outcomes

1

Description
Primary outcome of presence of renal scar in Dimercaptosuccinic acid renal scan

Timepoint
6-month follow-up

Method of measurement
Dimercaptosuccinic acid (DMSA) renal scan

Secondary outcomes

1

Description
The presence of kidney scar in children groups A and B with higher Procalcitonin and the acceptability of steroid adjuvant in terms of the amount of treatment and side effects
Timepoint
6-month follow-up
Method of measurement
Dimercaptosuccinic acid (DMSA) renal scan

Intervention groups

1

Description
Control group: They will receive only routine care
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sanandaj Mission Hospital
Full name of responsible person
Seyyed Zia Hijazi
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data file will be shareable after the approval of the research vice-chancellor of the faculty.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
There is no specific case.

From where data/document is obtainable
ziahejazi1933@gmail.com

What processes are involved for a request to access data/document
After receiving the application, the application will be submitted to the research vice-chancellor of the university, and if approved, the necessary information will be sent via email.

Comments