Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of vitamin A and Corticosteroid in reducing renal scarring in patients with acute pyelonephritis: a double-blind randomized clinical trial study with a control group

Protocol summary

Study aim

The aim of this study is to determine and compare the effects of vitamin A and Corticosteroid on the healing of scar tissue in patients with acute pyelonephritis.

Design

Study design: a parallel double-blind clinical trial (both patients and researchers) with a control group and in phase 3, with a sample size of 60 people, will be conducted on three groups of 20 patients with acute pyelonephritis, the first group being treated with vitamin A and the second group will be treated with corticosteroids. The third group also receives a placebo. In this study, the allocation of people to groups is done randomly with the help of ten blocks of letters A, B, C and using the Random Allocation software.

Settings and conduct

In the Nephrology Clinic of Imam Reza Hospital, Kermanshah, 60 eligible acute pyelonephritis patients are evaluated at the beginning of the study and 6 months later .

Participants/Inclusion and exclusion criteria

Inclusion criteria included diagnosis of acute pyelonephritis and hospitalization, children aged 3 months to 6 years, positivity of all urine cultures and exclusion criteria including lack of consent to participate in the study, neurogenic bladder, obstructive uropathy, intolerance Vitamin A and symptoms of vitamin A poisoning such as bad breath, hypotension, hypertension, apnea.

Intervention groups

Study intervention: Patients will be assigned to three groups to receive vitamin D (n=20), Corticosteroid (n=20) or placebo (n=20). Vials of vitamin D, Corticosteroid and placebo are similar in shape, color, and size.

Main outcome variables

The main outcome is the change in the severity of the kidney scar, which is evaluated by a nuclear scan at the beginning and end of the sixth month of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039715N5**
Registration date: **2023-04-16, 1402/01/27**
Registration timing: **prospective**

Last update: **2023-04-16, 1402/01/27**
Update count: **0**

Registration date

2023-04-16, 1402/01/27

Registrant information

Name

Sara Hookari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3826 4513

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin A and Corticosteroid in reducing renal scarring in patients with acute pyelonephritis: a double-blind randomized clinical trial study with a control group

Public title

Investigating the effect of vitamin A and coronet in the treatment of kidney scar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of acute pyelonephritis and hospitalization. Children aged 3 months to 6 years, All urine cultures are positive.

Exclusion criteria:

Lack of consent to participate in the study, neurogenic bladder, obstructive uropathy, Vitamin A intolerance, Symptoms of vitamin A poisoning,

Age

From **3 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in three equal groups (drug A, C, B) based on a randomized table with 10 blocks designed using Random allocation software (with one-to-one allocation). In order to randomly assign 60 patients to three groups, first, 6 blocks of 10 different letters A, C, and B are created, which respectively indicate the group treated with vitamin A, B the group treated with corticosteroids, and C the placebo group. Then these blocks were numbered with numbers one to six. In the next step, each of these blocks is randomly selected by drawing 6 times from numbers one to six. In this way, in each lottery, by choosing a block, a combination of 10 letters A (group treated with vitamin A), B (group treated with cortone) and C (placebo group) is obtained, and at the end of the 6 stages of the lottery Drawing, after selecting 6 blocks, a total of 6 combinations of 10 letters A and C B will be obtained. The combination obtained from the letters A, C, and B are placed individually in 6 separate envelopes and sealed, and one envelope is opened with each patient's visit to determine which group the patient belongs to take.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the drug and placebo are identical in terms of shape, color, smell, size, and packaging, participants, researchers, or outcome assessors will be unaware of study group allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermansha

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.KUMS.MED.REC.1401.277

Health conditions studied

1

Description of health condition studied

Acute pyelonephritis

ICD-10 code

N11.0

ICD-10 code description

Nonobstructive reflux-associated chronic pyelonephritis

Primary outcomes

1

Description

Change in severity of kidney scar

Timepoint

The beginning of the study (before the intervention), 6 months after the intervention

Method of measurement

by dimercaptosuccinic acid (DMSA) scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving vitamin A, manufactured by Osoeh Pharmaceutical Company of Iran, by injection during three days of hospitalization, three times in three days, and each injection of 25,000 units for children under one year and 50,000 units for children one year and older.
Category
Treatment - Drugs

2

Description
Intervention group:receiving corticosteroid (dexamethasone), manufactured by Tehran Shimi Pharmaceutical Company of Iran, by injection during three days of hospitalization, daily (0.15 mg/kg/day) in two divided doses.
Category
Treatment - Drugs

3

Description
Control group: receiving placebo (normal saline), produced by the Faculty of Pharmacy of Kermanshah University of Medical Sciences, by injection during three days of hospitalization, daily (0.15 mg/kg/day) in two divided doses.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital-Pediatric Nephrology Clinic
Full name of responsible person
Dr. Payam Mohamadi
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Sponsors / Funding sources

1

Sponsor
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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available