

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the effectiveness of Dexamethasone and Antibiotic therapy with Antibiotic and Placebo therapy in prevention of Renal scarring in children with Acute Pyelonephritis

Protocol summary

Study aim

Effects of dexamethasone on renal infection

Design

In this research, 60 eligible patients referring with acute pyelonephritis were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups

Settings and conduct

Double blind study at the children ward in the Boali sina hospital

Participants/Inclusion and exclusion criteria

Children with acute pyelonephritis, age 3m to 12 y.
exclusion previous renal anomaly.use of antibiotic and other organs disorder

Intervention groups

control group: antibiotic and placebo intervention group: antibiotic and dexamethasone

Main outcome variables

effect on the renal scar and urine cytokines

General information

Reason for update

Acronym

EARI

IRCT registration information

IRCT registration number: **IRCT20110531006660N4**

Registration date: **2017-12-27, 1396/10/06**

Registration timing: **retrospective**

Last update: **2017-12-27, 1396/10/06**

Update count: **0**

Registration date

2017-12-27, 1396/10/06

Registrant information

Name

Javad Ghafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 0054

Email address

ghafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences, Sari,Iran

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2013-10-22, 1392/07/30

Actual recruitment end date

2014-12-10, 1393/09/19

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Dexamethasone and Antibiotic therapy with Antibiotic and Placebo therapy in prevention of Renal scarring in children with Acute Pyelonephritis

Public title

Effect of Antibiotic in Renal infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of children with acute Pyelonephritis 3months to 12

years old

Exclusion criteria:
Previous urinary tract infection Urinary tract anomalies
renal failure renal scar Consumed antibiotic

Age
From **3 months** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual Simple Randomization with table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
Only the nurse that use drugs no blinded. But all of other people are blinded.

Placebo
Used

Assignment
Parallel

Other design features
Effect of Steroid on the Renal Scaring

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Moalem street , Moalem square

City
sari

Province
Mazandaran

Postal code
4815838477

Approval date
2013-08-08, 1392/05/17

Ethics committee reference number
1630

Health conditions studied

1

Description of health condition studied

children urinary tract infection

ICD-10 code

N00.9

ICD-10 code description

Acute nephritic syndrome with unspecified morphologic changes

Primary outcomes

1

Description

urinary IL6 and IL8 evaluate by ELISA

Timepoint

before and after treatment

Method of measurement

laboratory

2

Description

renal scaring

Timepoint

befor and 4 month after treatment

Method of measurement

isotop scan

Secondary outcomes

1

Description

drug side effects

Timepoint

during treatment

Method of measurement

Observation

Intervention groups

1

Description

Dexamethasone 0.15 mg/kg q6h and Ceftriaxone 80 mg/kg/day in intervention group for 4 days

Category

Treatment - Drugs

2

Description

Control group: 80 mg/kg/day ceftriaxone and placebo (normal saline) in control group fot 4 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Boalisina hospital
Full name of responsible person
Javad Ghaffari
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Pasdaran Blvd
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Recruitment center

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Boalisina hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Reza Alizadeh Navaei
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Moalem Sqaure
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Mazandaran
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4815858477
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Reza_nava@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Javad Ghaffari
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Allergy
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Person responsible for scientific inquiries

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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

All of data to be share after deidentified IPD.

When the data will become available and for how long

from 2018

To whom data/document is available

All people

Under which criteria data/document could be used

No limitation

From where data/document is obtainable

javadneg@yahoo.com

What processes are involved for a request to access data/document

quickly

Comments

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Subspecialist
Other areas of specialty/work
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