

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Study of the Effect of N-acetylcysteine Compared with Placebo on Inflammation Biomarkers of Acute Pyelonephritis in Children.

Protocol summary

Summary

In different studies, it has been shown that "antioxidant" utilization has favorable therapeutic effects not only on control of acute symptoms but also on prevention of delayed problems from acute and chronic pyelonephritis. According to the efficacy of N-acetyl cysteine as a potent antioxidant, safety of this drug and side effects of similar or either less than placebo, this study was designed to evaluate the efficacy of this drug on inflammatory biomarkers of pediatric acute pyelonephritis. It is a triple-blind placebo controlled study on a population of 64 patients 1-16 years old that have "definite" or "probable" diagnosis of acute pyelonephritis in "Mofid" hospital. After randomization, patients will be given N-acetylcysteine or placebo with dosing according to their weight. Results of treatment are evaluated according to serum procalcitonin, CRP and leukocyte count before drug prescription (baseline) and 5 days after drug prescription. Side effects are also recorded in both groups. Patients will be receiving their routine antimicrobial drugs in addition to N-acetylcysteine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112015465N1**

Registration date: **2014-01-21, 1392/11/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-21, 1392/11/01

Registrant information

Name

zahra allameh

Name of organization / entity

Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1273 6097

Email address

j.salamzadeh@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of N-acetylcysteine Compared with Placebo on Inflammation Biomarkers of Acute Pyelonephritis in Children.

Public title

Study of the Effect of N-acetylcysteine on Urinary Tract Infection in Children.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between the ages of 1 and 16; Having the diagnosis of "definite" or "probable" urinary tract infection according to guidelines of "pediatric infectious disease research center". Exclusion criteria: Patients younger than 1 or older than 16 years old;

Patients without the diagnosis of "definite" or "probable" urinary tract infection according to guidelines of "pediatric infectious disease research center"; Patients with acute/ chronic infectious or inflammatory diseases other than pyelonephritis.

Age

From **1 year** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study is a triple blind, placebo controlled trial. Patients, prescriber, researcher and statistical analyzer are blind in this trial. The main drug and placebo are very similar in terms of appearance, odor, flavor,....So they are Indistinguishable from each other by patients or prescriber. Coding of drugs will be done by another person other than prescriber, researcher and statistical analyzer. Codes are numbers 1-64.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Medical University, Faculty of Pharmacy

Street address

Vali-asr street

City

Tehran

Postal code

Approval date

2013-07-23, 1392/05/01

Ethics committee reference number

246

Health conditions studied

1

Description of health condition studied

Acute pyelonephritis

ICD-10 code

N10

ICD-10 code description

Acute tubulo-interstitial nephritis

Primary outcomes

1

Description

Serum procalcitonin

Timepoint

Before giving drug, and 5 days after giving the drug

Method of measurement

Serum procalcitonin test

2

Description

CRP

Timepoint

Before and 5 days after starting therapy

Method of measurement

Blood test

3

Description

Leukocyte count

Timepoint

Before and 5 days after starting therapy

Method of measurement

Blood test

Secondary outcomes

1

Description

Probable adverse effects (nausea, vomiting, bad tasting, stomatitis, ...)

Timepoint

Daily

Method of measurement

Clinical examination and asking from patients

Intervention groups

1

Description

Effervescent tablet of N-acethyl cystein 600 mg dosing according to weight, until 5 days. Dose for patients more than 30 kg: 1.5 tablet daily 8.5-30 kg: 1 tablet daily less than 8.5 kg: 70 mg/kg

Category

Treatment - Drugs

2

Description

Placebo effervescent tablet of N-acetyl cystein 600 mg dosing according to weight, until 5 days. Dose for patients more than 30 kg: 1.5 tablet daily 8.5-30 kg: 1 tablet daily: more than 30 kg: 1.5 tablet daily 8.5-30 kg: 1 tablet daily less than 8.5 kg: 70 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital, Infectious Disease and Nephrology Wards

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Medical University, Faculty of Pharmacy

Full name of responsible person

Research assistant of faculty of pharmacy, Shahid Beheshti Medical University

Street address

Faculty of pharmacy, lower than Niayesh intersection, Vali-asr street, Tehran, IR Iran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti Medical University, Faculty of Pharmacy

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Pediatric Infectious Research Center, Mofid Hospital

Full name of responsible person

Pediatric Infectious Research Center

Street address

Pediatric Infections Research Center , Ground Floor of Mofid Children Hospital, Shahid Beheshti University of Medical Sciences, Shariati Ave., Tehran, IR Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pediatric Infectious Research Center, Mofid Hospital

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Tehran, IR Iran.

Full name of responsible person

Zahra Allameh

Position

Clinical pharmacy resident

Other areas of specialty/work

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Faculty of pharmacy, lower than Niayesh intersection, Vali-asr street, Tehran, IR Iran.

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty