

# 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

##### Street address

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

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Zahra\_allameh@yahoo.comzahraallameh@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Faculty of pharmacy

##### Full name of responsible person

Zahra Allameh

##### Position

Clinical pharmacy resident

##### Other areas of specialty/work

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zahra\_allameh@yahoo.com

**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*