

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating N-acetylcysteine efficacy in the prevention of amphotericin B-induced nephrotoxicity

Protocol summary

Summary

The main aim of this study is to evaluate the efficacy of N-acetylcysteine in the prevention of amphotericin B-induced nephrotoxicity. Sixty adult patients are randomized to receive N-acetylcysteine (600 mg orally twice daily) (n = 30) or placebo (600 mg orally twice daily) (n = 30) during the period of amphotericin B treatment. Demographic data, primary admission diagnosis, concomitant disease(s) and co-administered medication(s) are recorded. Blood and urine sampling are performed at baseline (before starting amphotericin B) and weekly thereafter during amphotericin B treatment. Renal function test (blood urea nitrogen and creatinine), serum electrolytes (sodium, potassium, magnesium). In addition, novel markers of renal function (cystatin C and kidney injury molecule-1) are measured in serum samples at baseline, day 7, and 14 of amphotericin B treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107233449N8**

Registration date: **2011-08-09, 1390/05/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-08-09, 1390/05/18

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating N-acetylcysteine efficacy in the prevention of amphotericin B-induced nephrotoxicity

Public title

Evaluating N-acetylcysteine efficacy in the prevention of amphotericin B-induced nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age between 18 to 65 years 2- Hemodynamica stability (Mean arterial pressure > 70 mmHg and Systolic blood pressure > 90 mmHg) 3- Receiving AmB for treatment of fungal infections
Exclusion criteria 1- Documented history of acute kidney injury or chronic kidney disease 2- The status of kidney function at baseline is unknown 3- Receiving N-acetylcysteine (oral or parenteral) recently (during the last 1 month) 4- Documented history of hypersensitivity/anaphylactic reactions to N-

acetylcysteine 5- Co-administration of antioxidants (e.g. vitamin E, vitamin C)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Tehran University of Medical sciences, Central organization, 6th Floor

City

Tehran

Postal code

Approval date

2011-07-23, 1390/05/01

Ethics committee reference number

90-02-33-13767

Health conditions studied

1

Description of health condition studied

Fungal infections

ICD-10 code

B37, B38 ,

ICD-10 code description

Certain infectious and parasitic diseases

Primary outcomes

1

Description

Nephrotoxicity

Timepoint

At baseline then weekly

Method of measurement

renal function tests (BUN, Cr), serum electrolytes and biomarkers (cystatine C and KIM-1)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: N-acetylcysteine 600 mg orally twice daily

Category

Treatment - Drugs

2

Description

Control group: placebo 600 mg orally twice daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital affiliated to Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh saedi

Street address

Enghelab Ave, tehran university of medical sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for scientific inquiries

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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