Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison effect of intravenous sodium bicarbonate and sodium chloride combination versus intravenous sodium chloride hydration in reducing of amphotericin B-induced nephrotoxicity

Protocol summary

Study aim

Comparison effect of intravenous sodium bicarbonate and sodium chloride combination versus intravenous sodium chloride hydration in reducing of amphotericin B-induced nephrotoxicity

Design

A clinical trial with a control group with parallel groups, single-blind, randomized and sampling groups was 40 patients. In this study, there was no factor in the classification of patients in the two groups.

Settings and conduct

A randomized, single-blind clinical trial will be carried out at the Shiraz University of Medical Sciences , Namazi Hospital. BUN and Scr values will be determined for each patient every other day during the study period (days 1, 3, 5 and 7). GFR will be also calculated every other day by MDRD formula. Serum potassium and magnesium levels will be determined at days 1 & 7 of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 15 years, Receive amphotericin for at least 7 days, No history of kidney disease (including chronic kidney disease) and hemodialysis, Signing up the informed consent form Exclusion criteria: Cardiac failure class 3 and 4, Known liver failure, Known kidney failure, Alkalosis (pH greater than 7.5 or sodium bicarbonate plasma greater than 30 meq / lit), symptomatic Hypocalcemia, hypokalemia or hypomagnesemia, Sensitivity and any adverse effect that occurred after the injection of bicarbonate in the patient.

Intervention groups

group 1:Includes 20 patients with 1000 ml normal saline 0.9% equivalent to 159 mEq in two divided doses (500 ml) before and after infusion of amphotericin that is given to patients. group2:Includes 20 patients who received 500 ml of normal saline before injection of amphotericin and 1.5 vial sodium bicarbonate vial in 500 cc dextrose water, equivalent to the normal saline mEq 159, sodium bicarbonate that is given to patients.

Main outcome variables

Nephrotoxicity of amphotericin B

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161010030246N4**
Registration date: **2019-09-08, 1398/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-08, 1398/06/17**
Update count: **0**

Registration date

2019-09-08, 1398/06/17

Registrant information

Name
Iman Karimzadeh
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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karimzadee@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of intravenous sodium bicarbonate and sodium chloride combination versus intravenous sodium chloride hydration in reducing of amphotericin B-induced nephrotoxicity

Public title

Comparison effect of intravenous sodium bicarbonate and sodium chloride combination versus intravenous sodium chloride hydration in reducing of amphotericin B-induced nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 15 years Receive amphotericin for at least 7 days No history of kidney disease (including chronic kidney disease) and hemodialysis Signing up the informed consent form

Exclusion criteria:

Heart failure class 3 and 4 Known liver failure Known acute or chronic kidney disease Alkalosis (pH greater than 7.5 or sodium bicarbonate plasma greater than 30 meq / lit) Symptomatic hypocalcemia, hypokalemia or hypomagnesemia Sensitivity and any adverse effect that occurred after the injection of bicarbonate in the patient.

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Clinical trials are simple randomized, one-blind, and placebo-free that the patient did not know. The possibility of double-blind due to the lack of a clean room and the required facilities as well as the different appearance of sodium bicarbonate and sodium chloride Did not have. unit of randomization is individual a randomization method using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was conducted in a single blind setting that That the participants are blind in this study. It is impossible to conduct this clinical trial as double-blinded due to the lack of a clean room and the required facilities as well as the appearance of the sodium bicarbonate and sodium chloride looks different.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Street Karim Khan Zand

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.SUMS.REC.1398.460

Health conditions studied

1

Description of health condition studied

Nephrotoxicity

ICD-10 code

N10

ICD-10 code description

Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions

Primary outcomes

1

Description

Amphotericin b nephrotoxicity defined by either doubling of Scr from the baseline value or ≥50 % decrease in GFR

Timepoint

SCr and GFR are measured every other day during the intervention (Days 1, 3, 5 & 7).

Method of measurement

Measurement of serum creatinine using an autoanalyzer device

2

Description

Electrolyte disorders including hypokalemia (serum level potassium below 3 mEq/L) and hypomagnesemia (serum magnesium level below 1.2 mEq/L)

Timepoint

Serum potassium and magnesium levels are determined in the first and last days of the intervention (Days 1 & 7).

Method of measurement

Measurement of serum electrolytes using an autoanalyzer device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 20 patients who received 500 ml of normal saline before injection of amphotericin and 1.5 vial sodium bicarbonate vial in 500 cc dextrose water, equivalent to the normal saline mEq 159, sodium bicarbonate is given to patients.

Category

Prevention

2

Description

Control group: Includes 20 patients with 1000 ml normal saline 0.9% equivalent to 159 mEq in two divided doses (500 ml) before and after infusion of amphotericin is given to patients.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital of Shiraz

Full name of responsible person
Iman Karimzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Iman Karimzadeh

Position
Assistant professor

Latest degree
Specialist

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Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available