Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluating the effectiveness of pentoxifylline on the prevention of gentamicin nephrotoxicity in hospitalized patients in Shiraz

Protocol summary

Study aim
Determining the efficacy of pentoxifylline in the prevention of renal toxicity caused by gentamicin in hospitalized patients in Shiraz

Design
This study is a double-blinded, placebo-controlled, randomized clinical trial. The sample size is 60 patients. In this study, there is no factor in the classification of patients in the two groups.

Settings and conduct
A multi-center, randomized, double-blinded, placebo-controlled clinical trial is performed in Śhiraz educational hospitals such as Namazi and Shahid Faghihi. Serum creatinine, potassium, and magnesium levels are measured before starting gentamicin treatment (day 0) and days 1, 3, 5, and 7 of gentamicin treatment. Serum levels of malondialdehyde and TNF-α are measured before starting gentamicin treatment (day 0) and day 7 of gentamicin treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Receiving intravenous or intramuscular gentamicin for at least 1 week; Lack of confirmed acute or chronic kidney injury; Do not take gentamicin intravenously or intramuscularly during the past 14 days; Do not take pentoxifylline orally during the past week; Lack of confirmed history of allergic reactions to pentoxifylline; Signing up the informed consent form. Exclusion criteria: Patient with hemodynamic instability; Concomitant use of medicines or antioxidant compounds such as vitamin C, vitamin E, or vitamin A; Concomitant use of medications with high renal toxicity; Lack of oral tolerance to medications.

Intervention groups
Intervention group: Includes 30 patients, until gentamicin is prescribed, pentoxifylline sustained release 400 mg tablet (Farabi Pharmaceutical Company) is given orally three times a day. Control group: Includes 30 patients, until gentamicin is prescribed, placebo 400 mg tablet is given orally three times a day.

Main outcome variables
Gentamicin nephrotoxicity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161010030246N5**
Registration date: **2020-05-08, 1399/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**
Update count: **0**
Registration date
2020-05-08, 1399/02/19

Registrant information
Name
Iman Karimzadeh
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3242 4128
Email address
karimzadee@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-21, 1398/04/30
Expected recruitment end date
2020-07-20, 1399/04/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of pentoxifylline on the prevention of gentamicin nephrotoxicity in hospitalized patients in Shiraz

Public title

Evaluating the effectiveness of pentoxifylline on the prevention of gentamicin nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age higher than 18 years Receiving intravenous or intramuscular gentamicin for at least 1 week No confirmed acute or chronic kidney injury Do not take gentamicin intravenously or intramuscularly during the past 14 days Do not take pentoxifylline orally during the past week No confirmed history of allergic reactions to pentoxifylline Informed consent form

Exclusion criteria:

Patient with hemodynamic instability Concomitant use of medicines or antioxidant compounds such as vitamin C, vitamin E, or vitamin A Concomitant use of medications with high renal toxicity No tolerant of oral medications

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 15 blocks to select 60 people. We randomly select these blocks from the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the forth block. The people who enter the study are given B-A-A-B-A-A-B-B....., respectively. Finally, group A receives control intervention and group B receives treatment intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is unaware that the medicine given to the patient is the main medicine or placebo. The participant (patient) is also unaware that the medicine being given to them is the main medicine or placebo.

Placebo

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

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

711345-1978

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.SUMS.REC.1398.762

Health conditions studied

1

Description of health condition studied

Renal toxicity

ICD-10 code

N14

ICD-10 code description

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

Primary outcomes

1

Description

Gentamicin nephrotoxicity is defined by either a rise in the plasma creatinine concentration of more than 0.5 to 1 mg/dL

Timepoint

Serum creatinine is measured before starting gentamicin treatment (day 0) and days 1, 3, 5, and 7 of gentamicin treatment.

Method of measurement

Measurement of serum creatinine is done by using an autoanalyzer device.

2

Description

Hypokalemic electrolyte disorder (serum level potassium

below 3 mEq/L)

Timepoint

Serum potassium level are determined before starting gentamicin treatment (day 0) and days 1, 3, 5, and 7 of gentamicin treatment.

Method of measurement

Measurement of Serum potassium level is done by using an autoanalyzer device

3

Description

Hypomagnesemia electrolyte disorder (serum magnesium level below 1.2 mEq/L)

Timepoint

Serum magnesium level are determined before starting gentamicin treatment (day 0) and days 1, 3, 5, and 7 of gentamicin treatment.

Method of measurement

Measurement of Serum magnesium level is done by using an autoanalyzer device

Secondary outcomes

1

Description

Serum level of TNF-α

Timepoint

Serum level of TNF-α is measured before starting gentamicin treatment (day 0) and day 7 of gentamicin treatment.

Method of measurement

Measurement of TNF-α is done by the ELISA method.

2

Description

Serum level of malondialdehyde

Timepoint

Serum level of malondialdehyde is measured before starting gentamicin treatment (day 0) and day 7 of gentamicin treatment.

Method of measurement

Measurement of malondialdehyde is done by the ELISA method.

Intervention groups

1

Description

Intervention group: Includes 30 patients, until gentamicin is prescribed, pentoxifylline sustained release 400 mg tablet (Farabi Pharmaceutical Company) is given orally three times a day.

Category

Prevention

2

Description

Control group: Includes 30 patients, until gentamicin is prescribed, placebo 400 mg tablet is given orally three times a day.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz hospitals

Full name of responsible person

Iman Karimzadeh

Street address

Roknabad, Shiraz 5Km, Karafarin St., Faculty of Pharmacy

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 4127

Fax

+98 71 3242 4126

Email

karimzadee@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Shiraz University of Medical Sciences, Next to red Crescent, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 7282

Fax

+98 71 3235 7282

Email

ghasemiy@sums.ac.ir

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
Other areas of specialty/work
Medical Pharmacy
Street address
Shiraz-Roknabad-Karafarin street-Faculty of Pharmacy
City
Shiraz
Province
Fars
Postal code
7146864685
Phone
+98 71 3242 4128
Fax
+98 71 3242 4126
Email
karimzadee@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Iman karimzadeh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of clinical pharmacy,Namazi hospital,Namazi Squre
City
Shiraz
Province
Fars
Postal code
11351 – 71937
Phone
+98 71 3647 4332
Fax
+98 71 3647 4326
Email
karimzadee@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Ruhollah Mousavinasab
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Zand Avenue,Namazi Square, Namazi hospital,Shiraz
City
Shiraz
Province
Fars
Postal code
71937-11351
Phone
+98 71 3647 4332
Fax
+98 71 3647 4326
Email
mousavinasab@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available