Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Using novel biomarkers for detection and comparison of nephrotoxicity induced by various doses of amikacin in geriatric critically ill patients: A randomized clinical trial

Protocol summary

Summary
objective: to evaluate and comparison of nephrotoxicity induced by different doses of amikacin in geriatric critically ill patients. inclusion criteria: age equal to or more than 65 years; Sr cr equal to or less than 1.2 mg/dl; documented or suspicious gram negative sepsis; Exclusion criteria: renal failure; need for amikacin dosing adjustment; method: patients devided to 2 groups. on group recieve amikacin by dose of 25 mg/kg and another group recieve amikacin by 15 mg/kg dose. amikacin administered to patients for a minimum of 10 days and serum and urine samples foe mesurment of nephrotoxicity biomarkers and serum creatinin will be collected on baseline and days : 3, 5 ,7, 10. patients were analysed based on the rise in serum and urine biomarkers which can be a specific detector of renal damage.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2012091110817N1**
Registration date: **2013-01-24, 1391/11/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2013-01-24, 1391/11/05

Registrant information
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Kourosh Sadeghi
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2012-06-21, 1391/04/01
Expected recruitment end date
2013-06-22, 1392/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Using novel biomarkers for detection and comparison of nephrotoxicity induced by various doses of amikacin in geriatric critically ill patients: A randomized clinical trial

Public title
Detection of amikacin nephrotoxicity with novel markers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age equal to or more than 65; serum creatinin equal to or less than 1.2 or estimated GFR equal to or more than 40 ml/min; sepsis with gram negative or unknown microorganism in geriatric patients addmited in ICU and need for an aminoglycoside and no history of aminoglycoside administration in the last 30 days. Exclusion criteria: age less than 65; aminoglycoside administration in the last 30 days; BMI

more than 35; Allergy to aminoglycosides; amikacin administration less than 5 days; trouph levels more than 10 mcg/ml; need for amikacin dose adjustment during study period; neoplasm diagnisis with chemotherapy or radiotherapy history; viral hepatitis; moderate to severe renal failure considering normal decline in GFR with aging (Scr more than 1.2); life expectancey less than 48 hours and APACHE II score more than 35.

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research ethics comitee of Tehran University of Medical Sciences

Street address
Tehran University of Medical sciences, enghelab Sq, Tehran, Iran

City
Tehran

Postal code

Approval date
2012-11-18, 1391/08/28

Ethics committee reference number
91-03-33-19352-70727

Health conditions studied

1

Description of health condition studied
sepsis

ICD-10 code
A 41.5

ICD-10 code description
Sepsis due to other Gram-negative organisms

Primary outcomes

1

Description
Akutre kidney injury incidence

Timepoint
baseline and during drug administration on days: 3, 5 , 7, 10

Method of measurement
measurment of AKI biomarkers and serum creatinine

Secondary outcomes

1

Description
survival after 28 days post intervention in two groups

Timepoint
28 days after initiation of study

Method of measurement
report of survival or mortality on day 28

Intervention groups

1

Description
patients devided in 2 groups and in one group (high dose group) amikacin by dose of 25 mg/kg based on IBW will be administered to the patients. serum and urine samples will be collected on baseline and days 3.5.7. and 10 of the study

Category
Treatment - Drugs

2

Description
In second group (standard dose group) amikacin by dose of 15 mg/kg based on IBW will be administered for the patients for 10 days and serum and urine sampl;es will be collected on baseline and days 3,5,7, and 10 for analysis.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital- ICU general and ICU emergency wards- Tehran

Full name of responsible person
Mojtana Mojtahedzadeh

Street address

City
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2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital- Internal ICU- Tehran
Full name of responsible person
Kourosh Sadeghi
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3

Recruitment center
Name of recruitment center
Shohada hospital- ICU- Tabriz, Iran
Full name of responsible person
Hadi Hamishehkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Saeedi
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Vice Chancellor for Research- Tehran University of Medical Sciences- Keshavarz Blvd. Ghods St. TUMS central organization building. 4th floor.Research management department.
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

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Person responsible for updating data

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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