Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of N - acetylcysteine in the prevention of ototoxicity caused by vancomycin in the treatment of peritonitis in patients undergoing peritoneal dialysis.

Protocol summary

Summary

The aim of this study is to investigate the possible protective effects of N - acetylcysteine on the incidence of hearing damage caused by vancomycin in the treatment of peritonitis in patients undergoing peritoneal dialysis. Iinclusion criteria are the patients who undergoing peritoneal dialysis and have peritonitis. Exclusion criteria is the patients who have hearing damage before our study. After informed consent is obtained , 60 patients under peritoneal dialysis with peritonitis are enrolled. All patients treated by I.P. vancomycin within ISPD protocol. Patients were divided into two groups : Groups recving N - acetylcysteine (30 patients) and those who do not take N - acetylcysteine (30 patients). Patients undergoing audiometric studies at frequencies of 250 , 500 , 1000 , 2000 , 3000 , 4000 , 6000 and 8000. The control group treated with vancomycin and other group treated with I.P. vancomycin and N - acetylcystein oraly 600 mg BID. After 21 day treatment period , two groups undergoing audiometric studies and hearing impairment will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202148032N2**
Registration date: **2013-07-09, 1392/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-09, 1392/04/18

Registrant information

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Recruitment status

Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date

2012-09-28, 1391/07/07

Expected recruitment end date

2013-11-28, 1392/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N - acetylcysteine in the prevention of ototoxicity caused by vancomycin in the treatment of peritonitis in patients undergoing peritoneal dialysis.

Public title

Effect of N - Acetylcysteine in the prevention of ototoxicity caused by vancomycin.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Patients with peritoneal dialysis because of kidney problems ; Patients who do not use

ototoxic drugs ; Patients who have no previous hearing impairment Exclusion criteria : Baseline audiometry with hearing damage ; Patients who use other ototoxic drugs

Age
No age limit
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)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz - University Ave. - Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2012-12-17, 1391/09/27
Ethics committee reference number
91194

Health conditions studied

1

Description of health condition studied
Peritonitis
ICD-10 code
K65.9
ICD-10 code description
Peritonitis, unspecified

Primary outcomes

1

Description
Autotoxicity
Timepoint
Baseline and 21 days after treatment with N-acetylcysteine
Method of measurement
Audiometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: Receiving vancomycin intraperitoneal 1g q 5 days plus N – acetylcysteine 600 mg BID orally for 21 days.
Category
Treatment - Drugs

2

Description
Control: Receiving vancomycin intraperitoneal 1g q 5 days for 21 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic Of Nephrology, Imam Reza Hospital
Full name of responsible person
Sima Abediazar
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Imam Reza Hospital, Golgasht Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Assistance Of Tabriz University Of Medical Science
Full name of responsible person
Mohammad Reza Rashidi
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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
Research Assistance Of Tabriz University Of Medical Science
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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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