Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the protective effects of taurine against drug-induced toxicity in the patients treated by MTX, gentamicin and carbamazepin

Protocol summary

Summary

Gentamicim, an aminoglycoside antibiotic, is frequently used due to its high efficacy against microorghanisms. The principal side effect of this class of antibiotics is nephrotoxicity, which may occur in up to 20% of the exposed patients. It has been shown that, the generation of free oxygen radicals in renal cortex were enhanced by Gentamicin. The efficacy of methotrexate, a widely used cytotoxic chemotherapeutic agent in ALL, is often limited by severe side effects and toxic sequelae. The significant reduction in glutathione levels promoted by methotrexate leads to a reduction of effectiveness of the antioxidant enzyme defense system, sensitizing the cells to ROS. Carbamazepine is a tricyclic antiseizure drug effective in treatment of both and generalized tonic-clonic and partial seizures. A significant reduction in glutathione (GSH) levels has been reported by carbamazepine. The present study is undertaken to determine whether taurine, a potent free radical scavenger, could ameliorate drug-induced toxicity. In 72 patients who treated by MTX, gentamicin or carbamazepin, following a routine treatment, either placebo or taurine (2g/day P.O) will be administered. Hepatotoxicity, nephrotoxicity and hemotoxicity will be studied in both groups. Six blood samples will be obtained (every 2 months). Ototoxcity in gentamicin group will be studied by odiometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812123482N1**
Registration date: **2010-09-09, 1389/06/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-09-09, 1389/06/18

Registrant information

Name

Mina Islambulchilar

Name of organization / entity

Tabriz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor, Tabriz university of medical sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the protective effects of taurine against drug-induced toxicity in the patients treated by MTX, gentamicin and carbamazepin

Public title

Protective effects of taurine against MTX, gentamicin and carbamazepin's toxicity

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: taking oral MTX or gentamicin or carbamazepin. Exclusion criteria: drug sensitivity, drug side effects, asthma, smoking, death.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research vice chancellor, Tabriz university of medical scienses
Street address
Imam Khomeini St., Daneshgah St.
City
Tabriz
Postal code
Approval date
empty
Ethics committee reference number
8919

Health conditions studied

1

Description of health condition studied
Acute Lymphoblastic Leukemia
ICD-10 code
C81-C96
ICD-10 code description
Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

2

Description of health condition studied
Infactious deases treated by gentamicin
ICD-10 code
A30-A49
ICD-10 code description
Other bacterial diseases

3

Description of health condition studied
Seizure
ICD-10 code
G90-G99
ICD-10 code description
Other disorders of the nervous system

Primary outcomes

1

Description
hemoglobin
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

2

Description
leukocyte count
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

3

Description
TNF-a
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

4

Description
creatinin
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

5

Description
blood urea nitroge
Timepoint
6 blood samples , every 2 months
Method of measurement

biochemical methods

6

Description
alanine aminotransferase (ALT)
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

7

Description
aspartate aminotransferase (AST),
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

8

Description
myeloperoxidase (MPO) activity
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

9

Description
malondialdehyde (MDA),
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

10

Description
glutathione (GSH)
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

11

Description
hematocrit
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

12

Description
platelet
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

13

Description
taurine
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

14

Description
hearing power
Timepoint
3 times (basic, after discharge, 6 month later)
Method of measurement
odiometry

15

Description
liver function tests
Timepoint
6 blood samples , every 2 months
Method of measurement
biochemical methods

Secondary outcomes

1

Description
drug side effects
Timepoint
every 2 months
Method of measurement
taking history & physical examination

Intervention groups

1

Description
Control: placebo
Category
Placebo

2

Description
Intervention: taurine 2g/d
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology Oncology Research Center, Tabriz university of medical scienses

Full name of responsible person
Dr. Irag Asvadi
Street address
Imam Khomeini St., Daneshgah St.
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2

Recruitment center
Name of recruitment center
Research center of infectious disease & tropical medicine
Full name of responsible person
Dr. Mojtaba Varshochi
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3

Recruitment center
Name of recruitment center
Neurosciences research center
Full name of responsible person
Dr. Hormoz Ayromlou
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Daneshgah St., Emam Reza hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz university of medical scienses
Full name of responsible person
Dr. Rashidi
Street address
Imam Khomeini St., Daneshgah St., Research vice chancellor
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz university of medical scienses
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
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Person responsible for updating data

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Other areas of specialty/work

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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