

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

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

Protocol summary

Summary

Gentamicin, an aminoglycoside antibiotic, is frequently used due to its high efficacy against microorganisms. 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). Ototoxicity in gentamicin group will be studied by audiometry.

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

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 7459

Email address

islambulchilarm@tbzmed.ac.ir

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 sciences

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

Infectious 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

audiometry

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 sciences

Full name of responsible person

Dr. Irag Asvadi

Street address

Imam Khomeini St., Daneshgah St.

City

Tabriz

2**Recruitment center****Name of recruitment center**

Research center of infectious disease & tropical medicine

Full name of responsible person

Dr. Mojtaba Varshochi

Street address

Emam Reza hospital

City

Tabriz

3**Recruitment center****Name of recruitment center**

Neurosciences research center

Full name of responsible person

Dr. Hormoz Ayromlou

Street address

Daneshgah St., Emam Reza hospital

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz university of medical sciences

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 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****Contact****Name of organization / entity**

Tabriz university of medical sciences, Pharmacy school

Full name of responsible person

Dr Mohammadreza Ghandforoush-Sattari

Position

Assistant Professor of Clinical Toxicology/ PhD

Other areas of specialty/work**Street address**

Tabriz University of Medical Sciences, Daneshgah St.

City

Tabriz

Postal code**Phone**

+98 41 1337 2252

Fax**Email**

mrgsuk@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences, Pharmacy school

Full name of responsible person

Dr Mohammadreza Ghandforoush-Sattari

Position

Assistant Professor of Clinical Toxicology/ PhD

Other areas of specialty/work**Street address**

Tabriz University of Medical Sciences, Daneshgah St. Pharmacy school

City

Tabriz

Postal code**Phone**

+98 41 1337 2252

Fax**Email**

mrgsuk@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of pharmacology & toxicology, faculty of pharmacy, Tabriz university of medical sciences

Full name of responsible person

Mina Islambulchilar

Position

PhD candidate of toxicology / M.D

Other areas of specialty/work

Street address

Department of pharmacology & toxicology, faculty of
pharmacy, Tabriz university of medical sciences

City

Tabriz

Postal code**Phone****Fax****Email**

islambulchilarm@tbzmed.ac.ir ,
islambulchilar.mina@gmail.com

Web page address**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