

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Determination of therapeutic efficacy of N-acetyl cysteine with the combination of N-acetyl cysteine and Cimetidine in acute acetaminophen toxicity

Protocol summary

Summary

1) Objectives: Determination of the therapeutic efficacy of a combination of N-acetyl-cysteine (NAC) and cimetidine, in comparison with N-acetyl-cysteine alone, in acute acetaminophen toxicity. 2) Design: the present study is not belinded, randomized controlled trial. 3) The inclusion major criteria are: having para-clinical acetaminophen toxicity (toxic acetaminophen serum levels), and referring to the emergency poisoning department of Imam Reza Hospital, less than 8 hours from the poisoning. Exclusion major criteria are as follows: having multiple toxicities; simultaneous diseases affecting the liver enzymes (e.g. heart failure, congenital liver defects, and hepatitis); recent (less than a week) or regular consumption of other drugs; Those patients who didn't consent to the treatment, or were discharged from the hospital, were also excluded from the study. 4) Setting and conduct: among the patients admitted to the emergency department of Imam Reza Hospital, in the third quarter of 1392, those with suspected acetaminophen toxicity (according to the statements made by the patients, and their acquaintances, or the found evidence) were admitted to the hospital; if the clinical toxicity was approved, the patients were treated (based on the risk assessment nomogram of acetaminophen serum level), either with NAC or a combination of cimetidine injection + NAC . 5) interventions: N-acetyl-cysteine , a combination of N-acetyl-cysteine and cimetidine 6) main outcome: Serum acetaminophen levels, serum levels of aminotransferase

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102915204N1**
Registration date: **2014-01-01, 1392/10/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-01, 1392/10/11

Registrant information

Name

Farhad Bagherian

Name of organization / entity

Imam Reza Hospital, Emergency Department

Country

Iran (Islamic Republic of)

Phone

+98 51 1841 8890

Email address

bagherianf901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of therapeutic efficacy of N-acetyl cysteine with the combination of N-acetyl cysteine and

Cimetidine in acute acetaminophen toxicity

Public title

Comparing therapeutic efficacy of N-acetyl cysteine with the combination of N-acetyl cysteine and Cimetidine in acute acetaminophen toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion major criteria to study, are: having para-clinical acetaminophen toxicity (toxic acetaminophen serum levels), and referring to the emergency poisoning department of Imam Reza Hospital, less than 8 hours from the poisoning. Exclusion major criteria from study, are as follows: having multiple toxicities; simultaneous diseases affecting the liver enzymes (e.g. heart failure, congenital liver defects, and hepatitis); recent (less than a week) or regular consumption of other drugs; Those patients who didn't consent to the treatment, or were discharged from the hospital, were also excluded from the study.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Street, Ghoreishi Building, Mshhad

City

Mashhad

Postal code

Approval date

2013-07-03, 1392/04/12

Ethics committee reference number

920427/1/69

Health conditions studied

1

Description of health condition studied

Acute acetaminophen toxicity

ICD-10 code

T36, T37,

ICD-10 code description

Poisoning by drugs, medicaments and biological substances

Primary outcomes

1

Description

Serum level of acetaminophen

Timepoint

admission-next morning- discharging

Method of measurement

blood Sampling

Secondary outcomes

1

Description

Serum level of Serum aminotransferases

Timepoint

admission-next morning- discharging

Method of measurement

blood Sampling

Intervention groups

1

Description

Control group: N-acetyl cysteine patients are treated (based on the risk assessment nomogram of acetaminophen serum level)

Category

Treatment - Drugs

2

Description

Intervention group: the combination of N-acetyl cysteine and Cimetidine patients are treated (based on the risk assessment nomogram of acetaminophen serum level).
Cimetidine dose: 300 milligram every 6 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Imam Reza Hospital

Full name of responsible person

Farhad Bagherian

Street address

Imam Reza Square, Ebnesina Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ramezani

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Street, Ghoreishi Building, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Farhad Bagherian

Position

Resident

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Position

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

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Fax**Email****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