Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Mohammad Ebrahimi
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Web page address

Person responsible for updating data

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Farhad Bagherian
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Email
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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