Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the adverse effects of intravenous N-acetylcysteine with intravenous and oral N-acetylcystein in acetaminophen toxicity

Protocol summary

Summary

Acetylcysteine, also called N-acetylcysteine or NAC is the antidote for acetaminophen toxicity and it reduces morbidity and mortality following acetaminophen toxicity.Adverse drug reactions might affect therapeutic outcome or lead to treatment delay. In some countries NAC is given intravenously and in others orally. In our hospital the accepted route of administration is the intravenous route. In a previous study in our hospital, anaphylactoid reactions following intravenous NAC was found to be more than other studies, although there was no anaphylactoid shock or death. Moreover the oral route was not acceptable in patients because refractory emesis frequently leads to delayed or ineffective administration of the antidote. The longer duration of hospital stay in oral route is another factor makes our patients to accept the risk of anaphylactoid reactions than the oral administration. So we applied a new protocol using the combination therapy of both the oral and IV route for each patient and compared it with the only IV administration therapy (the accepted therapy in our hospital).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112146948N2**
Registration date: **2011-12-26, 1390/10/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-26, 1390/10/05

Registrant information

Name

Nastaran Eizadi-Mood

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the adverse effects of intravenous N-acetylcysteine with intravenous and oral N-acetylcystein in acetaminophen toxicity

Public title

Treatment of acetaminophen toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Patients with acetaminophen poisoning; ingesting the toxic acetaminophen dose (≥7.5g); aged ≥ 18 years old; coming to the hospital before 8 hours after acetaminophen ingestion. The exclusion criteria: Less than 7.5g acetaminophen ingesting; aged under 18 years old; coming to the

hospital after 8 hours after acetaminophen ingestion; vomiting two times after oral NAC was given; pregnant patients; those who had risk factors for hepatic toxicity (e.g. those who had hepatic cirrhosis; chronic ethanol ingestion; usage of substances that induce cytochrome P450 enzyme activity including rifampin; phenobarbital; isoniazid; phenytoin and carbamazepine).

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2009-03-02, 1387/12/12

Ethics committee reference number
185066

Health conditions studied

1

Description of health condition studied
acetaminphen toxicity

ICD-10 code
T39.0

ICD-10 code description
Poisoning by nonopioid analgesics, antipyretics and antirheumatics (Salicylate)s

Primary outcomes

1

Description
anaphylactoid reactions

Timepoint
during NAC (N-acetylcysteine) infusion

Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
The group A (only intravenous N-acetylcystein or NAC) was managed by IV NAC with 150mg/kg infused in 200cc of 5% dextrose water (5%DW) in 30 minutes, followed by a 4 hour infusion of 50mg/kg of NAC in 500cc of 5%DW and finally with a 16 hour infusion of 100mg/kg NAC in 1000cc 5%DW.

Category
Treatment - Drugs

2

Description
In group B (oral and IV NAC), oral NAC was given by 140mg/kg in 200cc of 5%DW. If vomiting occurred in any patient during one hour after the ingestion of the oral NAC then 10mg metoclopramide was given IM and the oral NAC was given with the same dose again. If there was no vomiting again then the administration of NAC was continued by IV route by 50mg/kg in 500cc of 5%DW in four hour infusion and then 100mg/kg in 1000cc of 5%DW in 16 hour infusion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Noor and Aliasghar Hospitals

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Isfahan 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

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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