Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Assessment of NAC's effect on coagulation tests (prothrombine time, Bleeding Time) in acute acetaminophen poisoning

Protocol summary

Summary

The purpose of this study determination the effect of N acetylcysteine on coagulation tests (BT, PT) in patients with acute acetaminophen poisoning admitted to hospital. This research is conducted as a clinical trial and Interventional. N-acetylcysteine is the main treatment in patients with acute acetaminophen poisoning. 36 patients were enrolled, in all patient who were history of acute acetaminophen poisoning with toxic dose (>7.5gram), immediately administered N- acetylcysteine as the standard dose. All the subjects received 218.75 mg/ kg N acetylcysteine for 8 hours after the start of treatment and 268.75 mg/ kg N acetylcysteine for 16 hours after the start of treatment. Prothrombin time and bleeding time test is performed in three steps from each patient that first admission and before treatment with N-acetylcysteine, the next 8 hours after treatment with N-acetylcysteine and the latest 16 hours after initiation of treatment. It is necessary to investigate whether therapeutic dose of NAC (N-acetylcysteine) itself can cause falsely increased prothrombin time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061218070N1**
Registration date: **2015-07-26, 1394/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

Name

Soheila Sadat Vaghefi

Name of organization / entity

Shahidbeheshti University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

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

Assessment of NAC's effect on coagulation tests (prothrombine time, Bleeding Time) in acute acetaminophen poisoning

Public title

Assessment of NAC's effect on coagulation tests in acute acetaminophen poisoning

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: the maximum time interval between consumption and arrive patient to hospital of 1-2 hours; acute acetaminophen poisoning; consumption more than 7.5 gram of acetaminophen; drugs containing acetaminophen without affecting liver function (adult

cold); age of more than14 years. Exclusion criteria: chronic acetaminophen poisoning; history of liver disease; history of Coagulopathy; coingestion; taking acetaminophen containing compounds with effects on liver function(eg.,acetaminophen codeine).

Age
From **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
N/A

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
Ethics Committee, Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Koodakyar St., Evin

City
Tehran

Postal code

Approval date
2013-02-03, 1391/11/15

Ethics committee reference number
0308/15696

Health conditions studied

1

Description of health condition studied
acute acetaminophen poisoning

ICD-10 code
x60

ICD-10 code description
Intentional self-poisoning by and exposure to nonopioid analgesics, antipyretics and antirheumatics

Primary outcomes

1

Description
Prothrombine time

Timepoint
Befor intervention, 8 hours after intervention, 16 hours after intervention

Method of measurement
Second, blood sample

2

Description
Bleeding time

Timepoint
Befor intervention, 8 hours after intervention, 16 hours after intervention

Method of measurement
Minute

Secondary outcomes

empty

Intervention groups

1

Description
In all patient who were history of acute acetaminophen poisoning with toxic dose (>7.5gram), immediately administered N - acetylcysteine as the standard dose. All the subjects received 218.75 mg/ kg N acetylcysteine for 8 hours after the start of treatment and 268.75 mg/ kg for 16 hours after the start of treatment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poisoning center, Shohadaye Haft Tir hospital

Full name of responsible person
Dr. Mohammad Ali Emam Hadi

Street address
Shahre Rey, Rajayi avenue

City
Shahre Rey

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Science, Koodakyar Avenue,Yaman Avenue, Chamran Highway
City
Tehran
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 of Shahid Beheshti 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
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Person responsible for updating data

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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