

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effects of oral and intravenous acetylcysteine in treating acetaminophen poisoning in admitted patients to poisoning emergency ward of Baharloo Hospital (2011-2012)

Protocol summary

Summary

This study is double blind randomized control trial in phase 4. Study population is referred patients to baharloos' hospital toxicological emergency ward. Samples allocated by randomized block sampling method in two standard (20-hour intravenous NAC protocol is 150 mg/kg loading dose over 15 minutes, followed by an additional dose of 50 mg/kg over 4 hours, and then 100 mg/kg over 16 hours, for a total dose 300 mg/kg) and experimental group (The 72-hour oral regimen is a 140-mg/kg loading dose followed by 70 mg/kg for 17 additional doses, for a total dose of 1330 mg/kg. Inclusion criteria: Patients over 18 year's old age which consume 7.5 gr acetaminophen during 24 hr ago will be concluding in the study. Exclusion criteria: Admission after 24 hr after consumption of acetaminophen, co ingestion of cholinergic drugs, primary unconsciousness, primary hepatic encephalopathy, presence of status epilepticus after NAC therapy, history of asthma and anaphylactoid reactions will considering as exclusion criteria. Acetaminophen serum concentration measured in the first of the study. Liver enzyme including AST, ALT and Prothrombin measured in the first of the study and for 72 hour Created complications and therapeutic effect will record and will compare by means of statistical analysis. Study duration is one-year from January 2012 to December 2012.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112218488N1**
Registration date: **2013-05-10, 1392/02/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-10, 1392/02/20

Registrant information

Name

Hamed Pouraziz Khasmakhi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of oral and intravenous acetylcysteine in treating acetaminophen poisoning in admitted patients to poisoning emergency ward of Baharloo Hospital (2011-2012)

Public title

Comparison of the effects of oral and intravenous acetylcysteine in treating acetaminophen poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Patients over 18 years old age which admitted to toxicological emergency ward of Baharloo hospital in Tehran which consume 7.5 gr acetaminophen during 24 hr ago will be conclude in the study. Inclusion Criteria: Patients over 18 years old age; consumption 7.5 gr acetaminophen during 24 hr before admittance Exclusion Criteria: Admission after 24 hr after consumption of acetaminophen; Co ingestion of cholinergic drugs; Primary unconsciousness; Primary hepatic encephalopathy; Presence of status epilepticus after NAC therapy; History of asthma and anaphylactoid reactions

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 in Research, Tehran University of Medical Sciences

Street address

Ethics committee in Research, Vice chancellor of Research, Keshavarz Blv

City

Tehran

Postal code

Approval date

2012-02-26, 1390/12/07

Ethics committee reference number

2348/130/90/3

Health conditions studied

1

Description of health condition studied

Acetaminophen Poisoning

ICD-10 code

T39.8

ICD-10 code description

Other nonopioid analgesics and antipyretics, not elsewhere classified

Primary outcomes

1

Description

AST

Timepoint

First of the study and 72 hour after treatment

Method of measurement

Serum concentration

2

Description

ALT

Timepoint

First of the study and 72 hour after treatment

Method of measurement

Serum concentration

3

Description

Bilirubin

Timepoint

First of the study and 72 hour after treatment

Method of measurement

Serum concentration

4

Description

Prothrombin time

Timepoint

First of the study and 72 hour after treatment

Method of measurement

Serum concentration

Secondary outcomes

1

Description

Treatment complication

Timepoint

At the first of the study up to 24 hour

Method of measurement

upon history and physical examination during treatment

Intervention groups

1

Description

Standard (20-hour intravenous NAC protocol is 150 mg/kg loading dose over 15 minutes, followed by an additional dose of 50 mg/kg over 4 hours, and then 100 mg/kg over 16 hours, for a total dose 300 mg/kg)

Category

Treatment - Drugs

2

Description

Experimental group (The 72-hour oral regimen is a 140-mg/kg loading dose followed by 70 mg/kg for 17 additional doses, for a total dose of 1330 mg/kg).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poisoning Emergency Ward, Bharloo Hospital

Full name of responsible person

Dr. Hamed Pouraziz

Street address

Behdari Sqr, Baharloo Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of School of Medicine, Tehran
University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Research Deputy, School of Medicine, Poursina Str

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of School of Medicine, Tehran
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

Tehran University of Medical Sciences

Full name of responsible person

Dr Hamed Pouraziz

Position

Assistant of Forensic Medicine

Other areas of specialty/work

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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