

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Treated with 12-Hour vs. 21-Hour Acetylcysteine Infusion in patients with acute poisoning due to acetaminophen referred to Isfahan Khorshid Hospital

Protocol summary

Study aim

Comparison of Treated with 12-Hour vs. 21-Hour Acetylcysteine Infusion in patients with acute poisoning due to acetaminophen referred to Isfahan Khorshid hospital

Design

A clinical trial with 2 intervention groups, with parallel groups, three-way blind, randomized, phase 3 on 80 patients. Excel software rand function was used for randomization

Settings and conduct

This study will be performed in Poisoning Emergency ward - at Khorshid hospital Isfahan. The principal investigator and the nursing staff have no knowledge about the selection of the patient as control or intervention, and only after selecting the patient based on the Excel round function, they prepare and prescribe medication..

Participants/Inclusion and exclusion criteria

Entry requirements : 1. Consent to participate in the study 2. Acetaminophen poisoning based on the toxic serum level of acetaminophen 3. Age between 13 to 60 years No entry conditions: 5. History of chronic liver and kidney patients 6. History of cancer and completion of chemotherapy 7. Take high-dose corticosteroids Concomitant use of drugs other than acetaminophen in toxic doses 9. Previous ECG disrupted

Intervention groups

Prescribing different treatment regimens of N-acetylcysteine in the two intervention groups in patients with acetaminophen poisoning

Main outcome variables

Length of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111003007710N2**
Registration date: **2022-06-08, 1401/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-08, 1401/03/18**

Update count: **0**

Registration date

2022-06-08, 1401/03/18

Registrant information

Name

Farzad Gheslaghi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1669 7823

Email address

gheshlaghi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Treated with 12-Hour vs. 21-Hour Acetylcysteine Infusion in patients with acute poisoning due to acetaminophen referred to Isfahan Khorshid Hospital

Public title

Acetylcysteine Infusion efficacy in patients with acute Acetaminophen poisoning I

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who referred to the poisoned emergency room of Khorshid Hospital in Isfahan after poisoning with a toxic dose of acetaminophen

Exclusion criteria:

History of chronic liver and kidney disease History of cancer and chemotherapy Take high doses of corticosteroids Concomitant use of drugs other than acetaminophen in toxic doses Previous unnormal ECG

Age

From **13 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the rand function in Excel software, a number is generated for each patient, if the number was even in the control group and if it was an odd number in the case group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The outcome assessor is not involved in the allocation process and selection groups and drug administrator, so he/she is blind. The statistician is unaware of the treatment performed in the two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Doesn't have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Isfahan University of Medical Sciences

Street address

Ostandari Ave. ,Khorshid Hospital

City

Isfahan

Province

Isfahan

Postal code

8145831451

Approval date

2022-05-17, 1401/02/27

Ethics committee reference number

IR.MUI.MED.REC.1401.066

Health conditions studied

1

Description of health condition studied

Acetaminophen poisoning

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood Acetaminophen level

Timepoint

Upon arrival, two hours before the end of the protocol, 24 hours and one week after discharge

Method of measurement

HPLC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the treatment protocol with NAC is 100 mg / kg in 200 cc of 5% dextrose serum during the first hour and then 200 mg / kg in 1000 cc of 5% dextrose serum for 10 hours.

Category

Treatment - Drugs

2

Description

Control group: group receiving NAC regimen for 21 hours, initial dose 150 mg / kg for 20 minutes, then 50 mg / kg for 4 hours and then 100 mg / kg for 16 hours

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Poisoning Emergency ward - Khorshid Hospital

Full name of responsible person

Nasim Tavakoli

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Ostandari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mansoor Siavash

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Hezar Jerib

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81746-73461

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research@mui.ac.ir

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Nasim Tavakoli

Position

Clinical Toxicology fellowship

Latest degree

Specialist

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available