

# 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

**Street address**

Ostandari

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8145831451

**Phone**

+98 31 3222 2255

**Fax**

+98 31 3222 2255

**Email**

Drnasimtavakoli@gmail.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Mansoor Siavash

**Street address**

Hezar Jerib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 7898

**Email**

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

**Street address**

Ostandari

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**Province**

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**Phone**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Farzad Gheslaghi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Toxicology

**Street address**

Ostandari

**City**

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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