

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Studying the effect of N-acetyl cysteine in cirrhotic patients

Protocol summary

Study aim

Given the increasing prevalence of cirrhosis and high burden of mortality and morbidity due to this condition, finding new effective agents to prevent the progression of the disease or slowing the rate of liver destruction and fibrosis. N-acetyl cysteine (NAC) have been approved for treatment of hepatic injury caused by acetaminophen toxicity. Recent animal studies have indicated the anti-inflammatory, anti-oxidant and anti-fibrotic effects of this drug. Thus in this study, we investigate the effects of NAC on hepatic function of cirrhotic patients.

Design

A randomized placebo-controlled double-blind clinical trial

Settings and conduct

All patients referred to the gastroenterology clinic in Taleghani Hospital with definitive diagnosis of liver cirrhosis that met inclusion criteria will be randomly divided into intervention and control groups. Demographic data and baseline tests, Child and MELD Score will be checked and calculated. All tests and Child-pugh and MELD Scores will be checked at the end of the 6 month period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-70 year-old patients with established diagnosis of cirrhosis with known etiology. Exclusion criteria: Patients with episodes of gastrointestinal bleeding and/or severe infections resulting in hospital admission at any time during the study period will be excluded.

Intervention groups

Intervention group: patients will receive 600 mg tablets of NAC twice a day. En Control group: Patients will receive placebo tablets completely similar to NAC tablets once.

Main outcome variables

Liver function evaluation by Child-Puff score system with scores categorized as A, B and C ; Liver function evaluation by MELD scoring system based on bilirubin and creatinine serum levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043734N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Maryam Masoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 1839

Email address

maryammasoumii666@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of N-acetyl cysteine in cirrhotic

patients

Public title
Studying the effect of N-acetyl cysteine in cirrosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Child suffering class A or B of cirrhosis Patients with score of 5-9 of child pugh score
Exclusion criteria:
Patient with class c of child pugh score

Age
From **18 years** old to **70 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
In this study, simple randomization, individually, will be performed using a sealed envelope by placing the patient numbers of 1 to 80 in two groups or the same in two envelopes. Only the researcher knows which group the envelopes and numbers belong to and allocation concealment will be double blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be aware of the effective intervention on health but without awareness of its type. The physician and researcher and data collector will be kept blind to the type of the intervention. The data analyzer is also kept blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1186

Health conditions studied

1

Description of health condition studied

cirrhosis

ICD-10 code

K74

ICD-10 code description

Cirrhosis

Primary outcomes

1

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Child-Puff score system with scores categorized as A, B and C

2

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

MELD scoring system based on bilirubin and creatinine serum levels

Secondary outcomes

1

Description

Kidney function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Creatinine level due to lab results

2

Description

Kidney function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Urea level due to lab results

3

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Aspartate Transaminase (AST) level due to lab results

4

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Alanine Aminotransferase (ALT) level due to lab results

5

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Total bilirubin level due to lab results

6

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Albumin level due to lab results

7

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Prothrombin time (PT) level due to lab result

8

Description

Liver function

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

International Normalized Ratio (INR) level due to lab result

9

Description

Blood parameter

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Hemoglobin level due to lab results

10

Description

Blood parameter

Timepoint

At the baseline and 6 months after starting N-acetylcysteine

Method of measurement

Platelet number due to lab results

Intervention groups

1

Description

Intervention group: patients will receive 600 mg tablets of NAC twice a day for 6 months

Category

Treatment - Drugs

2

Description

Control group: Patients will receive placebo tablets completely similar to NAC tablets twice a day for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Maryam Masoumi

Street address

Taleghani Educational Hospital, Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

City

Tehran

Province

Tehran

Postal code
1985711151
Phone
+98 21 2243 2560
Email
maryammasoumii666@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9780
Email
zarghi@sbmu.ac.ir
Web page address

Grant name

Shahid Beheshti University of Medical Science

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Masoumi
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work

Internal Medicine

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

maryammasoumii666@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Masoumi
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9770
Email
maryammasoumii666@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Masoumi
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran, Iran
City
Tehran
Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

maryammasoumii666@gmail.com

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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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