

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of N-acetylcysteine supplementation on psychological symptoms, oxidative stress, and inflammatory biomarkers in patients under methadone maintenance treatment

Protocol summary

Study aim

The aim of this study is to determine the effects of N-acetylcysteine supplementation on psychological symptoms, oxidative stress, and inflammatory biomarkers in patients under methadone maintenance treatment

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: among patients under methadone maintenance treatment referred to Sultan Mir Ahmad Clinic affiliated to Kashan University of Medical Sciences, 70 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Time of intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on methadone maintenance treatment and aged 18 to 50 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention: Patients will be assigned to receive either N-acetylcysteine (n=30) or placebo (n=30).

Main outcome variables

Depression; anxiety; sleep quality (primary outcome) and fasting plasma glucose; Insulin; triglycerides; total cholesterol; HDL; Hs-CRP; total antioxidant; glutathione; and malondialdehyde (secondary outcome).

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N10**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **prospective**

Last update: **2022-03-13, 1400/12/22**

Update count: **1**

Registration date

2020-09-19, 1399/06/29

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-20, 1399/06/30

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of N-acetylcysteine supplementation on psychological symptoms, oxidative stress, and inflammatory biomarkers in patients under methadone maintenance treatment

Public title

Effect of N-acetylcysteine supplementation in treatment of methadone maintenance treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under methadone maintenance treatment Age of 18 to 50 years old Evaluated by the drug abuse section of the Structured Clinical Interview for DSM-IV

Exclusion criteria:

Unwillingness to cooperate Consumption of antioxidant, and anti-inflammatory supplements during the last 3 months High blood pressure Hypothyroidism or hyperthyroidism Pregnant women

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2020-05-19, 1399/02/30

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.017

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Depression

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Beck Depression Inventory (BDI)

2

Description

Anxiety

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Beck Anxiety Inventory (BAI)

3

Description

Sleep quality

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes**1****Description**

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2**Description**

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

3**Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4**Description**

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5**Description**

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

6**Description**

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

7**Description**

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

8**Description**

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9**Description**

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

10**Description**

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group: tablet of N-acetylcysteine, 600 mg (Ave sina, Tehran, Iran), four oral tablet for 12 weeks.

Category

Treatment - Drugs

2**Description**

Control group: placebo tablet (Ave sina, Tehran, Iran), four oral tablet for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Soltan Mirahmad Clinic

Full name of responsible person

Amir Ghaderi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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<http://research.kaums.ac.ir/Default.aspx?PageID=58>

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

No

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Amir Ghaderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Ph.D of addiction

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Latest degree

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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

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