

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of N-acetyl cysteine as an adjuvant therapy on Symptoms and Progression of Parkinson's disease

Protocol summary

Study aim

Evaluation of the efficacy of prescribing N-acetylcysteine on Parkinson's disease patients

Design

A Clinical trial with two experimental groups (Intervention group and Control group), two-side blinded, randomized based on randomized four-block allocation, on 40 Patients with Parkinson's disease

Settings and conduct

This is a study on Parkinson's disease patients, referred to Tohid Hospital of Sanandaj City. The patients receive N-acetylcysteine for one year. The efficacy of the Drug is evaluated based on clinical interview, filling Unified Parkinson's Disease Rating Scale (UPDRS) questionnaire, and single-photon emission computerized tomography (SPECT) brain imaging. The only person who has not been blinded for the study is the supplier of the drug and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's informed consent
Exclusion criteria: Having brain surgery within a year before the initiation of the intervention

Intervention groups

Medication group (receiving 1200 mg N-acetylcysteine per day, twice daily, each time 600 mg) placebo group (receiving a placebo with similar appearance, color, odor, and taste like real medication)

Main outcome variables

Movement and mood symptoms of the patients,
Metabolic Activity of Substantia nigra region of brain in the Patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041247N1**

Registration date: **2021-01-03, 1399/10/14**

Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Arman Rahimmi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4643

Email address

arman_s_life@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2018-04-09, 1397/01/20

Actual recruitment end date

2020-09-21, 1399/06/31

Trial completion date

2021-12-22, 1400/10/01

Scientific title

Effect of N-acetyl cysteine as an adjuvant therapy on Symptoms and Progression of Parkinson's disease

Public title

Effect of N-acetyl cysteine on Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's informed consent No brain surgery in the patient's post medical history

Exclusion criteria:

having brain surgery within a year before starting the treatment period

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is based on making blocks with size of 4 people, to divide participants into two groups: intervention group (A) and control group (B). So that, we divide all participants to four-sample blocks, and we allocate the block's samples equally between the two groups (e.g. ABAB). This pattern is the same in all blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, clinical caregivers, outcome evaluators and data analyzers are not aware whether the therapeutic regimens include the drug or placebo. only the main researcher and pharmacist are aware of nature of therapeutic regimen based on codes given to the drug and placebo packages, earlier.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Avenue

City

Sanandaj

Province

Kurdistan

Postal code

6617913446

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.MUK.REC.1397.348

Health conditions studied

1

Description of health condition studied

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

The quality of the patient's movement skills and intellectual function

Timepoint

Before and after the invention (one year)

Method of measurement

Filling the Unified Parkinson's Disease Rating Scale (UPDRS) questionnaire according to the patient's interview and examining

2

Description

Changes in dopaminergic areas within the patient's brain

Timepoint

Before and after the invention (one year)

Method of measurement

Technetium-99m-Trodat-1 single-photon emission computerized tomography (SPECT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Parkinson's disease patients receive N-acetylcysteine for one year. two times per day, every time 600 mg. The medicine is consumed after breakfast and after dinner (one time per 12 hours). The medicine is made by Zambon Company, Switzerland.

Category

Treatment - Drugs

2

Description

Control group: Parkinson's disease patients receive the placebo for one year, two times per day. The placebo is consumed after breakfast and after dinner (one time per 12 hours).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Arman Rahimmi

Street address

Geryashan Street

City

Sanandaj

Province

Kurdistan

Postal code

6616812131

Phone

+98 87 3328 6112

Email

armanrahimmi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki, Vice-Chancellor for Research and Technology, Kurdistan University of Medical Sciences

Street address

3rd floor, Medicine School, Kurdistan University of Medical Sciences, Pasdaran Ave.

City

Sanandaj

Province

Kurdistan

Postal code

6617913446

Phone

+98 87 3366 4643

Email

maleki43@yahoo

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Arman Rahimmi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Amir Nezam Garoosi Street, Shahrak-e-Rah-o-Tarabari, Moalem Blvd., Feyz Abad Distict

City

Sanandaj

Province

Kurdistan

Postal code

6614988796

Phone

+98 87 3316 2929

Email

armanrahimmi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Arman Rahimmi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Amir Nezam Garoosi Street, Shahrak-e-Rah-o-Tarabari, Moalem Blvd., Feyz Abad Distict

City

Sanandaj

Province

Kurdistan

Postal code

6614988796

Phone

+98 87 3316 2929

Email

armanrahimmi@gmail.com

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

Sanandaj University of Medical Sciences

Full name of responsible person

Arman Rahimmi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Amir Nezam Garoosi Street, Shahrak-e-Rah-o-Tarabari, Moalem Blvd., Feyz Abad Distict

City

Sanandaj

Province

Kurdistan

Postal code

6614988796

Phone

+98 87 3316 2929

Email

armanrahimmi@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Only a part of the data, probably Analyzed data can be accessed.

When the data will become available and for how long

The accession period is 6 months and starts after publishing the study results

To whom data/document is available

Researchers, Industry

Under which criteria data/document could be used

The data can be used only for scientific citations. Any other use needs the permission of the RCT authorities.

From where data/document is obtainable

Arman Rahimmi, Phone number: +989183718474, Email: armanrahimmi@gmail.com

What processes are involved for a request to access data/document

After communicating with Dr. Arman Rahimmi, the request will be processed within two weeks and the request will be responded according to the decisions.

Comments