Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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 Sbstantia 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