Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Study of the efficacy and safety of nano curcumin as an adjuvant to antipsychotics in male patients with residual schizophrenia: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Assessment of the efficacy and safety of adding Nano-Curcumin to antipsychotic treatment regimen in improving positive, negative, general and cognitive symptoms in patients with chronic schizophrenia

Design

A randomized, double-blind, placebo-controlled clinical trial, design of 40 patients with chronic schizophrenia (1: 1 in each group) at 4 months

Settings and conduct

Care centers in Mazandran province

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years old men with the diagnosis of schizophrenia based on DSM-5 criteria for at least two years and despite the anti-psychotic drug treatment, they are still symptomatic. They are treated with antipsychotics for at least one year and In the last month, the type and dosage of their antipsychotic drugs remain constant. If receiving medications such as mood stabilizer or anti depressants, their type and dosage will remain constant from one month before the start of the study and during the study.

Intervention groups

Intervention group: standard treatment regimen with two nanocurcumin capsule 80mg (sinacurcumin@) that produced by the Nanotechnology Research Center of Mashhad University of Medical Sciences and distributed by Exir Nano Sina Company in Tehran, in two divided dose. Control group: standard regimen with two placebo capsule that are similar to nanocurcumin capsules for odor, taste, size and color in two divided dose.

Main outcome variables

Assessment of PANSS; Calgary Depression Scale for Schizophrenia; CGI-I; CGI-S; Brief Assessment of Cognition in Schizophrenia (BACS) at baseline and at the end of each months. Assessment of safety by using weekly BARS, SAS and AIMS Scales. Check of the profile lipid and fasting blood glucose at baseline and end of study. Measuring patient weight at the beginning of the study and the end of each month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N5**
Registration date: **2018-05-14, 1397/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-14, 1397/02/24**
Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy and safety of nano curcumin as an adjuvant to antipsychotics in male patients with residual schizophrenia: A randomized, double-blind, placebo-controlled trial

Public title

The effect of nano curcumin in male patients with residual schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years old men With the diagnosis of schizophrenia based on DSM-5 criteria for at least two years and despite the anti-psychotic drug treatment, they are still symptomatic. They are treated with antipsychotics for at least one year and In the last month, the type and dosage of their antipsychotic drugs remain constant. If receiving medications such as mood stabilizer or anti depressants, their type and dosage will remain constant from one month before the start of the study and during the study.

Exclusion criteria:

Patients with acute suicidal behavior or history of suicide attempt last year, the presence of psychiatric disorders such as schizoaffective or other psychotic disorders, Mental retardation or other cognitive impairment, bipolar disorder and depression, anxiety disorders such as current panic disorder or obsessive-compulsive disorder, post traumatic stress disorder, eating disorder. History of drug dependence (DSM-5 drug dependency criterion) or substance abuse during the three months prior to the onset of the study or positive urine specimen testing at the start of the study. ECT therapy in the past six months. People with thoughts or attempted to harm themselves or others at baseline and at 6 months before the start of the study. Mental retardation Patients with neurological disorders such as uncontrolled seizure, dementia, head injury, seizure disorder (other than febrile) and neurodegenerative diseases (such as Alzheimer's disease, Parkinson's disease, stroke, and multiple sclerosis) Patients with uncontrolled illnesses such as cardiovascular disease-liver and kidney failure-types of malignancies-autoimmune diseases, endocrine disorders such as diabetes, and hematological disorders, chronic diseases such as cardiovascular disease, history of myocardial infarction, severe hypertension, excessive overweight due to endocrine disorder, unstable thyroid disease, biliary diseases, consuming sex hormones, cerebrovascular diseases, benign prostatic hypertrophy, glaucoma, asthma, COPD, chronic fatigue syndrome, Fibromyalgia and any unstable medical condition. Receiving anticoagulant and antiplatelet treatments or having hemorrhagic risk factors, having an infectious disease during last month, the likelihood of not being able to complete a study because of a serious illness. No more than once a week to take analgesics and do not use turmeric and curcumin supplements and no use of turmeric in the diet. Sensitivity to the curcumin plant or any of the available placebo compounds. History of NMS Patients treated with anticholinergic drugs (except of biperiden and trihexyphenidyl) according to drugs on the Anticholinergic Burden scale (ACB)

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers and 1: 1 ratio in treatment group and control group

Blinding (investigator's opinion)

Double blinded

Blinding description

Curcumin and placebo capsules are completely similar in terms of color, size, smell and taste produced by a completely similar manufacturing and packagings. Patients were randomly tested in groups. Until the end of the study, no patient or study persons are aware of which drug the patient receives. And anybody other than those who are defective in the study is aware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی مازندران

Street address

Moallem street, Moallem square, Vice chancellor for research

City

Sari

Province

Mazandaran

Postal code

33971-48157

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.MAZUMS.REC.97.83

Health conditions studied

1

Description of health condition studied

Schizophrenia with residual symptoms

ICD-10 code

F20.5

ICD-10 code description

Residual schizophrenia

Primary outcomes

1

Description

Score of general, positive and negative symptoms with Positive and Negative Symptom Scale (PANSS)

Timepoint

At baseline and the end of each month

Method of measurement

Positive and Negative Symptom Scale (PANSS)

Secondary outcomes

1

Description

Score of change in severity of illness based on Clinical Global Impression – Improvement (CGI-I)

Timepoint

At baseline and the end of each month

Method of measurement

Clinical Global Impression -Improvement (CGI-I) score

2

Description

Score of severity of illness based on Clinical Global Impression of Severity (CGI-S)

Timepoint

At baseline and at the end of each months

Method of measurement

Clinical Global Impression off Severity (CGI-S)

3

Description

Score of depression symptoms based on Calgary Depression Scale for Schizophrenia

Timepoint

At baseline and the end of each month

Method of measurement

Calgary Depression Scale for Schizophrenia

4

Description

Score of improvement in cognitive symptoms based on Brief Assessment of Cognition in schizophrenia

Timepoint

At baseline and the end of the each months

Method of measurement

Brief Assessment of Cognition in schizophrenia

5

Description

Score of SAS for extra pyramidal side effects

Timepoint

At baseline and weekly

Method of measurement

Simpson-Angus Scale (SAS)

6

Description

Score of Barnes Akathisia Rating Scale (BARS)

Timepoint

At baseline and weekly

Method of measurement

Barnes Akathisia Rating Scale (BARS)

7

Description

Score of Abnormal Involuntary Movement Scale (AIMS)

Timepoint

At baseline and weekly

Method of measurement

Abnormal Involuntary Movement Scale (AIMS)

8

Description

Lipid profile

Timepoint

At baseline and the end of study

Method of measurement

ELIZA Kit

9

Description

Fasting blood glucose

Timepoint

At baseline and the end of study

Method of measurement

ELIZA Kit

10

Description

Weight

Timepoint

At baseline and the end of each month

Method of measurement

Scale

Intervention groups

1

Description
Intervention group: Standard treatment regimen with two nanocurcumin capsule 80mg (sinacurcumin@) in two divided dose for four months.
Category
Treatment - Drugs

2

Description
Control group: Standard treatment regimen with two placebo capsule that are similar to nanocurcumin capsules for odor, taste, size and color in two divided dose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric care centers in Mazandaran province
Full name of responsible person
Narjes Hendouei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Moallem street, Moallem square-Vice chancellor for research
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tmaae@liv.ac.uk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Mazandaran University of Medical Sciences
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Narjes Hendouei
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I have not decided yet - its release plan is still unclear

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable