

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Study of the effect of Memantine on negative symptoms and inflammatory biomarkers (IL6, TNFa CRP) in patients with schizophrenia or schizoaffective disorders

Protocol summary

Summary

Schizophrenia is compromised of several debilitating symptoms. Antipsychotics offer an effective treatment for positive symptoms, while the negative sign and cognitive deficits are usually treatment-resistant. It was suggested that glutamate dysregulation may be involved in the neuropathology of schizophrenia, mainly through NMDA dysfunction. We hypothesized that addition of memantine, a weak non-selective NMDA receptor antagonist approved for dementia, to antipsychotics would improve the clinical status of unremitted schizophrenia patients, notably the negative sign and cognitive deficits. In this double-blind, placebo-controlled study, participants (59 patients) were assigned to receive placebo or memantine (once daily), in dosing titration as follows: week 1, 5mg/day; week 2, 10 mg/day; weeks 3-8, 20 mg/day, in addition to continuing treatment with antipsychotics for 8 weeks. The primary efficacy measure was the total score on positive and negative symptom scale (PANSS) and secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310083210N5**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

mariatavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Memantine on negative symptoms and inflammatory biomarkers (IL6, TNFa CRP) in patients with schizophrenia or schizoaffective disorders

Public title

Study of the effect of Memantine on negative symptoms and inflammatory biomarkers (IL6, TNFa CRP) in patients with schizophrenia or schizoaffective disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18-65 years old; patients

that base on DSM V criteria has diagnosis of schizophrenia or schizoaffective disorder; patients who stable on medication four weeks prior to baseline and has not planned medication change. Exclusion criteria: subject that organic brain disease or neurological diagnosis (including neurological disorder or an active seizure); subjects who will meet the criteria for DSM-V diagnosis of alcohol or substance dependence within the last six month; any change of psychotropic medication within the previous four weeks.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **59**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences,
Faculty of Pharmacy

Street address

Vali-asr ave., Niayesh highway

City

Tehran

Postal code**Approval date**

2015-07-26, 1394/05/04

Ethics committee reference number

SBMU2.REC.1394.62

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

PANSS score

Timepoint

At baseline, at the end of first and third month of the study

Method of measurement

Questionair

2**Description**

Clinical evaluation

Timepoint

At baseline, at the end of first and third month of the study

Method of measurement

Questionair

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

Assessment of inflammatory biomarkers (IL6, TNF, CRP)

Timepoint

At baseline, at the end of first and third month of the study

Method of measurement

ELISA

2**Description**

Assessment of inflammatory biomarkers (IL6, TNF, CRP)

Timepoint

At baseline, at the end of first and third month of the study

Method of measurement

ELISA

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

Patients will receive memantine (once daily), in dosing titration as follows: week 1, 5mg/day; week 2, 10 mg/day; weeks 3-8, 20 mg/day, in addition to continuing tretment with antipsychotics for 8 weeks.

Category

Treatment - Drugs

2

Description

Patients will receive placebo in control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Maria Tavakoli Ardekani

Street address

Velenjak street, Shaheed Chamran highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Maria Tavakoli Ardakani

Street address

Vali-asr ave., Niayesh high way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamide Abbaspour

Position

Resident of clinical pharmacy

Other areas of specialty/work

Street address

Valiasr Ave., Niayesh highway

City

Tehran

Postal code

Phone

+98 11 4203 1035

Fax

Email

dr.abbaspour1@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Maria Tavakoli Ardakani

Position

Associate professor, Academic member / PhD

Other areas of specialty/work

Street address

Valiasr Ave., Niayesh highway

City

Tehran

Postal code

Phone

+98 21 8820 0085

Fax

Email

mariatavakoli@yahoo.com; mariatavakoli@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Hamideh Abbaspour

Position

Resident of clinical pharmacy

Other areas of specialty/work

Street address

Valiasr Ave., Niayesh highway

City

Tehran

Postal code

Phone

+98 11 4203 1035

Fax

Email

dr.abbaspour1@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty