Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 approve for dementia, to antipsychotics would improve the clinical status of un-remitted schizophrenia patient, notably the negative sign and cognitive deficits. in this double- blind, placebo controlled study, participants (59 patient) 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 tretment with antipsychotics for 8 weeks. The primary efficacy measures was the total score on positive and negative symptom scale (PANSS) and secondry 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, Shaid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, Faculity 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 recieve 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
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Velenjak street, Shaheed Chamran highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of pharmacy, Shahid Beheshti University of Medical Scienses
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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 Scienses
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

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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