Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of vitamin B complex and placebo as adjunctive therapy on positive, negative and cognitive symptoms in patients with chronic schizophrenia; A double-blind randomized clinical trial.

Protocol summary

Study aim
Evaluating the efficacy of vitamin B complex add-on therapy on treatment of positive, negative and cognitive symptoms in patients with chronic schizophrenia.

Design
Double-blind randomized interventional clinical trial; Phase 3 on 50 patients; For 3 months; With parallel groups; Web-based software http // www.Randomization.com was used for randomization.

Settings and conduct
The statistical population includes patients with schizophrenia in Razi Psychiatric Hospital. The study is double-blind in which participants, researchers, psychologists and psychiatrists will be blind and only the executor is aware of the division into two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: schizophrenia; not having any psychiatric disorder other than schizophrenia; Patients receiving atypical antipsychotic medication; Having IQ in the normal range; Obtain informed consent from the patient. Non-inclusion criteria: having any debilitating physical illness; Substance or drug abuse in the past six months; Receive ECT in the last two weeks; Contraindications to vitamin B complex

Intervention groups
In this study, two groups were considered, patients who received B complex and patients who received placebo

Main outcome variables
Positive symptoms including delirium, hallucinations, disintegration of associations, strange behavior, disturbed speech; Negative symptoms including superficial emotions, poor speech or content of speech, obstruction of thinking, inappropriate makeup and appearance, lack of motivation, lack of pleasure, social withdrawal; Cognitive symptoms including working memory deficits, cognitive impairment and attention deficit

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210428051118N1**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **retrospective**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date
2021-08-06, 1400/05/15

Registrant information

Name
Somayeh Aqmasheh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7716 6396

Email address
aqmasheh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-18, 1400/03/28

Expected recruitment end date
2021-07-05, 1400/04/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of vitamin B complex and placebo as adjunctive therapy on positive, negative and cognitive symptoms in patients with chronic schizophrenia; A double-blind randomized clinical trial.

Public title
Efficacy of vitamin B complex add-on therapy on positive, negative and cognitive symptoms of chronic schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from Schizophrenia Do not have any other psychiatric disorder other than schizophrenia, for which a structured interview by a psychiatrist and the patient's test results are used Patients receiving atypical antipsychotic drug Having IQ in the normal range by measuring IQ by Raven test Obtain informed consent from the patient or his / her guardian
Exclusion criteria:
Having any physically debilitating disease, whether prominent neurological or organic, including severe kidney and liver disease, for which a clinical examination by a physician and the patient's test results are used. Misuse of drugs or medications in the last six months Receive ECT in the last two weeks Patients who are contraindicated in vitamin B complex consumption
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Http://www.Randomization.com software was used to randomly divide people into two groups
Blinding (investigator's opinion)
Double blinded
Blinding description
Capsules of the same shape were used for this purpose
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of University of Rehabilitation and Social Sciences
Street address
University of Social Welfare and Rehabilitation Sciences, Koodkiar St., Daneshjoo Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2021-06-13, 1400/03/23
Ethics committee reference number
IR.USWR.REC.1400.082

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
loosening of association
Timepoint
When entering the study, the end of the fourth, eighth and twelfth week
Method of measurement
PANSS (Positive And Negative Syndrome Scale)

2

Description
delirium
Timepoint
When entering the study, the end of the fourth, eighth and twelfth week
Method of measurement
PANSS (Positive And Negative Syndrome Scale)

3

Description

Delusion

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale)

4

Description

Strange behavior

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale)

5

Description

Disorganized speech

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale)

6

Description

flat or blunted affect

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

7

Description

Poverty of speech or poverty of content of speech

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

8

Description

Thought blocking

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

9

Description

inappropriate makeup and appearance

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

10

Description

avolition

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

11

Description

anhedonia

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

12

Description

social withdrawal

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

PANSS (Positive And Negative Syndrome Scale),Calgary Depression Scale for Schizophrenia

13

Description

working memory problems

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

Raven IQ Test,Montral Cognitive Assessment:MoCA

14

Description

cognitive impairment

Timepoint

When entering the study, the end of the fourth, eighth and twelfth week

Method of measurement

Raven IQ Test,Montral Cognitive Assessment:MoCA

15

Description
attention deficit
Timepoint
When entering the study, the end of the fourth, eighth and twelfth week
Method of measurement
Raven IQ Test،Montral Cognitive Assessment:MoCA

Secondary outcomes

empty

Intervention groups

1

Description
Control group: One placebo capsule daily (purchased from Poursina Pharmaceutical Company) , which is similar to the main drug in color, smell and taste, is added to their treatment regimen for three months.
Category
Treatment - Drugs

2

Description
Intervention group: One Bcomplex vitamin capsule daily (purchased from Poursina Pharmaceutical Company) is added to their treatment regimen for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Somayeh Aqmasheh
Street address
Aminabad, Shahid Rastegar Boulevard, Taghiabad intersection, Shahreri
City
Tehran
Province
Tehran
Postal code
18664
Phone
+98 21 3340 1220
Email
razi.pr@uswr.ac.ir
Web page address
https://razi.uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamid Reza Khankeh
Street address
University of Social Welfare and Rehabilitation Sciences, Koodkiar St., Daneshjoo Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 2218 0083
Email
hamid.khankeh@ki.se
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of Social and Rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Somayeh Aqmasheh
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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University of social welfare and rehabilitation sciences
Full name of responsible person
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Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available