

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](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

Psychiatrics

Street address

Narmak

City

Tehran

Province

Tehran

Postal code

1649739834

Phone

+98 21 7709 2854

Fax

Email

aqmasheh@gmqil.com

Person responsible for scientific 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

Psychiatrics

Street address

Narmak

City

Tehran

Province

Tehran

Postal code

1649739834

Phone

+98 21 7709 2854

Fax**Email**

aqmasheh@gmqil.com

Person responsible for updating data**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

Psychiatrics

Street address

Narmak

City

Tehran

Province

Tehran

Postal code

1649739834

Phone

+98 21 7709 2854

Fax**Email**

aqmasheh@gmqil.com

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