Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Study of the efficacy and safety of Nigella sativa (black seed) as an adjuvant to antipsychotics in patients with chronic schizophrenia: A 6-week, randomized, double-blind, placebo-controlled trial

Protocol summary

Summary

In this study, the aim is to determine whether adding Nigella sativa (black seed) to the standard therapeutic regimen of schizophrenic patients could improve some aspects of the symptom burden or not. This study is a 6-week randomized, double-blind, placebo-controlled trial.Fifty patients with chronic stable schizophrenia with residual symptoms are randomly divided into the intervention and control groups. Simple randomization based on a random-numbers table is used to assign subjects to either the placebo or the intervention group. Subjects in the intervention group receive an initial dose of 500 mg/day on the three fist days, which is increased to 1000 mg/day on the fourth day and continue with the same dose until the end of the study along with their antipsychotic regimen .The control group receive their antipsychotic regimen alone for six weeks. Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression of Severity (CGI-S), Clinical Global Impression of Improvement (CGI-I) and Calgary Depression Scale for Schizophrenia are assessed at the baseline and on the third and sixth weeks. All schizophrenic patients are managed based on the guidelines of the American Psychiatric Association. The diagnosis is made by two psychiatrists independently, according to the DSM-V criteria .During the study period, only co- medication with anticholinergic drugs and benzodiazepines are allowed. Positive and Negative Syndrome Scale (PANSS), Calgary Depression Scale for Schizophrenia ، for the severity of depressed mood assessment and the Clinical Global Impression Severity and Improvement scales (CGI-S and CGI-I) are assessed at baseline and weeks 3 and 6.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012832236N1**
Registration date: **2017-02-06, 1395/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-02-01, 1395/11/13

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the efficacy and safety of Nigella sativa (black seed) as an adjuvant to antipsychotics in patients with chronic schizophrenia: A 6-week, randomized, double-blind, placebo-controlled trial

Public title
Nigella sativa effect in the treatment of residual symptoms in patients with schizophrenia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- Male or female inpatients in two long-stay Psychiatric Care and Rehabilitation Centers which are Supervised by Iranian Rehabilitation Institute located in Sari in the north of Iran 2- 18–65 years at the time of screening 3- With a diagnosis of schizophrenia(paranoid, disorganized, catatonic, or undifferentiated type)or schizoaffective disorder, based on the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Five Edition(DSM-V)and they are suffering from the disease for more than 2 years with residual symptomatology despite antipsychotic treatment 4- All patients are on antipsychotics for at least 1 year and a stable dose for at least 2 month are included in the trial and the antipsychotics dose remain unchanged during the trial. 5- Mood stabilizers (lithium and divalproex) and antidepressants (only the selective serotonine reuptake inhibitors (SSRIs) venlafaxine, and mirtazapine) were permitted as part of antipsychotic pharmacotherapy. Dose of these drugs must be stable for at least 2 month remain unchanged during the trial. Exclusions criteria: 1- Acute relapse (As acute relapse was defined an impending decompensation based on a PANSS score of ≥4 (moderately) on the subscore items of hostility and uncooperativeness and/or a ≥20% increase in the PANSS total score. 2- Psychiatric comorbidity(primary or secondary diagnosis of bipolar I disorder, either manic or mixed episode, as defined by Diagnostic and Statistical Manual of Mental Disorders, Five Edition(DSM-V)) 3- History of substance dependence (including alcohol, but excluding nicotine) as defined by Diagnostic and Statistical Manual of Mental Disorders, Five Edition(DSM-V)and relapse within the past 6 months, or substance abuse within the 3 months preceding the trial or positive urine test for illicit drugs 4- Electroconvulsive therapy during the 6 past months 5- Suicidality(active suicide or homicide intent, or a suicide or homicide attempt in the preceding 6 months) 6- Mental retardation 7- Pregnant or at risk of pregnancy 8- Cognitive disorders such as dementia, delirium, or amnesia, traumatic brain injury 9- Current significant unstable medical illness (such as unstable cardiac disease, hepatic or renal impairment, evidence or history of malignancy or any significant hematological, endocrine)/ HIV infection / abnormalities on physical examination, vital signs, electrocardiogram (ECG), or clinical laboratory values 10- Hypersensitivity to Nigella sativa 11- Previous treatment with Nigella sativa in the past year 12- History of neuroleptic malignant syndrome 13- Unwilling or unable, in the opinion of the Investigator, to comply with study instructions

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Mazandaran University of Medical Sciences

Street address
Farahabad Road,Payambare azam complex

City
Sari

Postal code

Approval date
2016-08-19, 1395/05/29

Ethics committee reference number
IR.MAZUMS.REC.95.2232

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20.5

ICD-10 code description
Residual schizophrenia

Primary outcomes

1

Description
Severity of psychiatric symptoms assesment

Timepoint

at baseline and weeks 3 and 6

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

1

Description

Depressed mood assessment

Timepoint

baseline and weeks 3 and 6

Method of measurement

Calgary Depression Scale for Schizophrenia

2

Description

Clinical Global Impression of Improvement (CGI-S)

Timepoint

baseline and weeks 3 and 6

Method of measurement

Clinical Global Impression of Improvement (CGI-S)

3

Description

Clinical Global Impression of Improvement (CGI-I)

Timepoint

baseline and weeks 3 and 6

Method of measurement

Clinical Global Impression of Improvement (CGI-I)

4

Description

Nigella sativa induced akathisia assessment

Timepoint

baseline and weeks 3 and 6

Method of measurement

Barnes Akathisia Scale

5

Description

Nigella sativa induced Movement disorder assessment

Timepoint

baseline and weeks 3 and 6

Method of measurement

Simpson–Angus Scale

6

Description

Nigella sativa induced Movement disorder assessment

Timepoint

baseline and weeks 3 and 6

Method of measurement

Abnormal Involuntary Movement Scale

Intervention groups

1

Description

Subjects in the intervention group receive an initial dose of 500 mg/day on the three fist days, which is increased to 1000 mg/day on the fourth day and continue with the same dose until the end of the study for six weeks along with their antipsychotic regimen

Category

Treatment - Drugs

2

Description

The control group receive their antipsychotic regimen with one placebo capsule on the three fist days, which is increased to two placebo capsule/day on the fourth day and continue until the end of the study for six weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare hospital

Full name of responsible person

Narjes Hendouei

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Moallem street-Moallem square-Vice chancellor for research Sari

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

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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