Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of Adalimumab in the treatment of patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
Studying the effect of Adalimumab in the treatment of patients with chronic schizophrenia

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be performed on patients with chronic schizophrenia attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of positive and negative symptoms based on DSM-5; attending hospital with a psychosis attack; age between 18 to 60 years old. Exclusion criteria: head trauma; history of shock therapy during past three months prior to the trial; undergoing neurosurgery; presence of acute or chronic systemic diseases; history of allergy to the medication used in this research; receiving any anti-psychotic medications during past eight weeks prior to the trial.

Intervention groups
Patients with chronic schizophrenia (based on DSM-5 diagnostic criteria) are included in the study and divided into two control (25 participants) and intervention (25 participants) groups. Participants in the intervention group receive Adalimumab subcutaneous injection (40 mg) by pen-injector at weeks 0 and 4, and participants in the control group receive placebo at weeks 0 and 4. Using Positive and Negative Symptoms Scale (PANSS), patients' positive and negative symptoms are assessed at weeks 0, 4 and 8. The side effects of Adalimumab will also be evaluated and compared. Also, at weeks 0 and 8 of the study, blood samples will be taken from patients and IFN-γ, IL-1β, IL-6, IL-8 levels will be measured and compared in two groups.

Main outcome variables
Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N126**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**
Update count: **0**

Registration date
2020-05-17, 1399/02/28

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 5541 2222

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of Adalimumab in the treatment of patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Public title
The effect of Adalimumab in the treatment of patients with chronic schizophrenia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of positive and negative symptoms based on DSM-5 Attending hospital with a psychosis attack Age between 18 to 60 years old

Exclusion criteria:
Head trauma History of shock therapy during past three months prior to the trial Undergoing neurosurgery Presence of acute or chronic systemic diseases History of allergy to the medication used in this research Receiving any anti-psychotic medications during past eight weeks prior to the trial

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

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Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-12-27, 1398/10/06

Ethics committee reference number
IR.TUMS.VCR.REC.1398.1003

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Severity of schizophrenia

Timepoint
Baseline and weeks 4 and 8

Method of measurement
By Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Subcutaneous injection of Adalimumab (40 mg) (CinnaGen, Tehran) by pen-injector at weeks 0 and 4

Category
Treatment - Drugs

2

Description
Control group: Subcutaneous injection of normal saline as placebo at weeks 0 and 4
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Prof. Mohammad Reza Mohammadi
Street address
Roozbeh Hospital, South Kargar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of Medical 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
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
Professor of clinical psychopharmacology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The data will be distributed through final report

When the data will become available and for how long
5 years from 2021 to 2026

To whom data/document is available
academic researchers

Under which criteria data/document could be used
users should cite the resource of data

From where data/document is obtainable
Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document
by E mail

Comments