

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of therapeutic efficacy of treatment with olanzapine and halopridol on regional cerebral blood flow measured by SPECT in patients with schizophrenia, correlating with the response to treatment

Protocol summary

Summary

The aim of this study is to evaluate the rCBF of the schizophrenic patients treated with olanzapine and halopridole in a within-subject and between-subject design. Thirty patients with schizophrenia are participating in the study. Each subject will be scanned and assessed according to PANSS and CGI in a medication-free state. All patients are randomly allocated in two groups. One group is being treated with fixed dose of 15 mg/day olanzapine and the other with 10 mg halopridole. All assessments will be repeated after 4 weeks of treatment. Also a group of 12 cases without any history of neurological or psychological disorder are enrolled as a control group for comparing of the SPECT data. The changes in pattern of regional perfusion will be evaluated between control and two groups of patient subjects and also in each patients group before and after treatment. The correlation between clinical improvement and rCBF changes in each groups after treatment will also be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706051100N1**

Registration date: **2011-08-16, 1390/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-16, 1390/05/25

Registrant information

Name

Davood Beiki

Name of organization / entity

Research Institute for Nuclear Medicine, Tehran
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2007-01-10, 1385/10/20

Expected recruitment end date

2008-11-11, 1387/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic efficacy of treatment with olanzapine and halopridol on regional cerebral blood flow measured by SPECT in patients with schizophrenia, correlating with the response to treatment

Public title

Treatment of schizophrenia with antipsychotic drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the criteria of DSM-IV for schizophrenia; neuroleptic drug-naïve or drug-free for at

least 4 weeks; age range from 18-58 years; filling consent form; no drug tranquilization for at least five half life of the drug; no psychoactive drug therapy for at least 5 half life of the drug. Exclusion criteria: Accompanied disorders of axis 1 or 2 based on DSM-IV; evidence of neurological disease; History of any drug abuse; elevating hepatic enzymes; pregnancy; thyroid dysfunction; consumption of drugs interfering with HT25 or D2 receptors.

Age

From **18 years** old to **58 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz boulevard

City

Tehran

Postal code

-

Approval date

2006-11-14, 1385/08/23

Ethics committee reference number

85-02-30-3805

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

alteration in cerebral perfusion

Timepoint

one month after using the drug

Method of measurement

cerebral perfusion scan

Secondary outcomes

1

Description

Changes in severity of clinical symptoms

Timepoint

one month after onset of the treatment

Method of measurement

PANSS and CGI tests for clinical symptom score

Intervention groups

1

Description

Olanzapine 10 mg/da

Category

Treatment - Drugs

2

Description

Haloperidole 10 mg/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Nuclear Medicine and Roozbeh Hospital, Tehran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical

Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tehran 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

Research Institute for Nuclear Medicine, Tehran
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Full name of responsible person

Dr Babak Fallahi

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Associate Professor of Nuclear Medicine

Other areas of specialty/work

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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