Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 schizopherenia; neuroleptic drug-naive or drug-free for at

least 4 weeks; age range from 18-58 years; filling consent form; no drug tranqulization 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 interferring 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
Schizopherenia

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

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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