Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the efficacy of Raloxifine and Isradipine in cognitive impairment of schizophrenic patients

Protocol summary

Summary

Improving neurocognitive physiopathological aspect of schizophrenia is a current challenge to identify the pathway to develop goal directed clinical interventions in practice. Aims and objectives: In the present study we will examin the effect of Raloxifine as a selective estrogen modulator and Isradipine as a voltage gated L type calcium channel blocker on improvement of schizophrenic patients cognitive deficits. We designed and performed double blind randomized clinical trials in Zanjan province. 60 patients with schizophrenia or schizoaffective diagnosis, without intellectual disability and systolic blood pressure higher than 100 mmHg and Diastolic pressure above 60 mmHg will recruit in 3 specific groups, will receive 2 times a day, Isradipine capsule 5 mg or Raloxifine tablet 60 mg or placebo in each group. The drugs were given to the patients in capsules with the same color and shape for 6 consequent weeks alongside treatment with conventional antipsychotics. Patients with comorbid chronic diseases in DSM-V axis I, history of life time abuse of substance and any other neurological disorders will be excluded. Initial and final lab data such as (INR, PT, FSH, LH, ALT, AST, ALK, TSH, T3, T4), ECG, positive and negative syndrome scale as well as cognitive tests in specific domains such as attention, processing speed, executive function, verbal memory will be investigated then comparison between groups will be checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010225812N1**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name
Bita Vahdani
Name of organization / entity
Zanjan University of Medical Sciences, Shahid Beheshti Hospital
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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2017-09-28, 1396/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Raloxifine and Isradipine in cognitive impairment of schizophrenic patients

Public title

Comparison of Raloxifene and Isradipine Administration in Improvement of Schizophrenic Patients' Cognitive Deficits.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: All enrolled patients will have normal IQ ; systolic blood pressure more than 100 mmHg ; diastolic blood pressure more than 60 mmHg ; at least 2 years diagnosis of schizophrenia or schizoaffective disorder according to DSM-V diagnostic criteria.
Exclusion Criteria: patients with any other comorbidity of psychiatric or neurologic disorders ; history of lifetime substance abuse ; any sensitivity to drugs ; history of head trauma or loss of consciousness ; resistant high blood pressure ; resistance in treatment of schizophrenia or beginning Clozapine ; renal, liver or cardiac failure ; women' s pregnancy or breast feeding ; any abnormality in ECG ; suicide idea ; history of dementia ; breast cancer ; tromboemboli events ; dementia ; endocrine disease ; history of receiving ECT during last 12 months.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethic committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Postal code

4515613191

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

zums.rec.1394.332

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20,

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

2

Description of health condition studied

Schizoaffective,

ICD-10 code

F25,

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description

Attention

Timepoint

baseline and week 6

Method of measurement

The Stroop Color and Word test

2

Description

Executive Function

Timepoint

baseline and week 6

Method of measurement

The Wisconsin Card Sorting Test (WCST)

3

Description

Processing Speed

Timepoint

baseline and week 6

Method of measurement

Wechsler Digit Coding Task, Symbol III

4

Description

Memory

Timepoint

baseline and week 6

Method of measurement

Wechsler, Verbal Memory test

5

Description

Structured Clinical Interview for the DSM-V (SCID)

Timepoint

baseline and week 6

Method of measurement

Psychiatry resident will interview to confirm diagnosis for inclusion into study

Secondary outcomes

1

Description

PT, PTT, INR

Timepoint

baseline and week 6

Method of measurement

Blood sample

2

Description

LH, FSH, Vit D3

Timepoint

baseline and week 6

Method of measurement

blood sample

3

Description

Side effect self report form

Timepoint

Up to 6 weeks

Method of measurement

Patient report

4

Description

Change in ECG

Timepoint

Baseline and week 6

Method of measurement

ECG to confirm inclusion into study and compared at week 6 to baseline

5

Description

Change in chemistry panel (TSH, T3, T4)

Timepoint

Baseline and week 6

Method of measurement

Blood sample

6

Description

AST, ALT, ALKP

Timepoint

baseline and week 6

Method of measurement

Blood sample

Intervention groups

1

Description

Tablet Raloxifine 60 mg, Two times a day, 6 weeks,

Category

Treatment - Drugs

2

Description

Capsule Isradipine 5 mg, 2 Times a day, 6 weeks

Category

Treatment - Drugs

3

Description

Capsule Placebo, 2 times a day, 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Psychiatry Hospital,

Full name of responsible person

Dr. Bita Vahdani

Street address

Are Square, Beheshti Hospital, Department of Pychiatry

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Zanjan University of Medical Sciences

Full name of responsible person

Dr. Shoghli, finance and administrative research affair

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanajn

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 of Zanjan 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
Zanjan University of Medical Sciences
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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