Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The study of sertraline in controlling the resistant hypertension in women with co-morbid premenstrual syndrome

Protocol summary

Summary

In this study 40 referring women to heart clinics of Tabriz university of medical sciences with resistant HTN will be studied. All these women should be diagnosed with PMS according to DRSP test in 2 consequent months and should be included considering the inclusion & exclusion criteria and signing the written informed consent form . Screening the psychiatric patient will be also done according to SADS questionnaire ,Screening the psychiatric patient will be also done according to SADS questionnaire , all patient will be randomly divided into two control and intervention groups in a double blind study . the two groups will be matched regarding age and drug dosage . no patient will take extra anti-hypertensive drug . the intervention group will be treated by 50 – 100 mg sertraline for 4 – 6 weeks while the control group will be treated by placebo for the same time period . The blood pressure re control for both groups will be done by a 24 hour tonoport after 4 – 6 weeks . The results will be analysis by SPSS statistical program with paired samples T test and Independent samples T test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904092181N4**
Registration date: **2010-06-30, 1389/04/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-06-30, 1389/04/09

Registrant information

Name

Fatemeh Ranjbar Kouchaksaraei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 6923

Email address

ranjbarf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of sertraline in controlling the resistant hypertension in women with co-morbid premenstrual syndrome

Public title

The Effect of sertraline in women with resistant hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Sex age, Age 15 – 49 year old, presence of drug resistant hypertension, With PMS (premenstrual syndrome), With written informed consent form Exclusion criteria: history of allergic reaction or side

effect with sertaline, BMD (bipolar mood disorder), MDD (major depressive disorder), anxiety disorders, psychosis, cognitive disorders, or mental retardation, Pregnancy, breast feeding, Acute coronary syndromes, Heart failure

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
vice chancellor for research of tabriz university of medical sciences

Street address
Tabriz-golgasht streat-tabriz medical sciens univercity

City
Tabriz

Postal code

Approval date
empty

Ethics committee reference number
8916

Health conditions studied

1

Description of health condition studied
Recurrent depressive disorder, unspecified

ICD-10 code
F33.9

ICD-10 code description
Monopolar depression NOS

2

Description of health condition studied
hypertension

ICD-10 code
I10

ICD-10 code description
High blood pressure

Primary outcomes

1

Description
Blood pressure

Timepoint
Before / 4-6 weeks after intervention

Method of measurement
Blood pressure mannometer (mmHg)

Secondary outcomes

1

Description
Sertraline side effect

Timepoint
Weekly

Method of measurement
Antidepressant side effects questionnaire

Intervention groups

1

Description
Interventional group: tab sertraline 50 -100 mg daily for 4 -6 weeks

Category
Treatment - Drugs

2

Description
Control group: placebo with the same shape, size and taste for 4–6 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bozorgmehr psychiatric clinic

Full name of responsible person
Dr Fatemeh Ranjbar Kouchaksaraie, Psychiatrist, Associate professor

Street address
Bozorgmehr psychiatric clinic, Speacial clinics of Tabriz University of Medical Sciences,

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz medical sience university
Full name of responsible person
vice chancellor for research
Street address
Tabriz-golgasht streat-tabriz medical sciens univercity-central building nomber2-third flour - vice chancellor for research
City
Tabriz
Grant name
124/202
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz medical sience university
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
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Web page address

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