

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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 sertraline, 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 street-tabriz medical sciences university

##### 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 manometer (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, Special clinics of Tabriz University of Medical Sciences,

**City**  
Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz medical science university

**Full name of responsible person**

vice chancellor for research

**Street address**

Tabriz-golgasht street-tabriz medical sciences  
university-central building number2-third floor - 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 science 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Ranjbar Kouchaksaraie

**Position**

Psychiatrist-Associate professor

**Other areas of specialty/work**

**Street address**

Razi hospital, El goli road, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1380 4486

**Fax**

**Email**

ranjbarf@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific

## inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Ranjbar Kouchaksaraie

**Position**

Psychiatrist-Associated professor

**Other areas of specialty/work**

**Street address**

Razi hospital, El goli road, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1380 4486

**Fax**

**Email**

ranjbarf@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mahboob Asadlo

**Position**

Psychiatric resident

**Other areas of specialty/work**

**Street address**

Razi hospital, El goli road, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

**Fax**

**Email**

mahboobasadlo@yahoo.com

**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*