

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Pregnancy outcomes with chronic hypertetion on different antihypertensive therapy

Protocol summary

Summary

The aim of this study is control and treatment of chronic hypertension in pregnancy. Also, improve outcomes of fetal and maternal. 80 pregnant women with chronic hypertension for prenatal care that referring to Al-Zahra hospital from the date of approval of plan to complete the sample collection will be included and in the absence of consent to participate will be excluded from study. Blood pressure is measured at each visit with adult standard sphygmomanometer. Blood pressure tried to be preserved between 90/140 to 100/150. If blood pressure is higher than 109/159, anti-hypertensive therapy with methyldopa 250 mg every 12 hours is starting and 3 days later will visit again. If blood pressure is higher than 100/150, we add a dose and if we got to 4 tablets per day and at weekly intervals of control of blood pressure 10 mg Hydralazine tablets will added every 12 hours and if necessary increase the dose. If treatments in next controls are not effective, we will use Nifedipine. Dosage adjustment is in order to maintain blood pressure between 100-90/150. In the meantime, at every visit, maternal and perinatal outcomes will be monitored. Maternal outcomes included: HELLP Syndrome, stroke, acute kidney injury, heart failure, placental abruption and maternal mortality. Prenatal outcomes included: fetal death, growth restriction, preterm delivery, fetal death, neonatal morbidity. In case of bad consequences, the mother is hospitalized and further evaluation and treatment measures are done. For each patient, type of prescribed medication, dose, the number of divided doses, time and bad consequences of maternal and perinatal will be recorded. Based on the research question, Patients in need with Anti-hypertensive medicine less than 5 divided doses or 5 or more than 5 is divided into two groups. Undesirable outcomes of maternal and perinatal among two groups are compared. This study is not blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602067676N5**

Registration date: **2016-02-23, 1394/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-23, 1394/12/04

Registrant information

Name

Simin Taghavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

taghavis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2016-02-15, 1394/11/26

Expected recruitment end date

2017-02-14, 1395/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pregnancy outcomes with chronic hypertetion on different antihypertensive therapy

Public title

Pregnancy outcomes with chronic hypertetion on different antihypertensive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: pregnant women with chronic hypertension. Exclusion criteria: absence of consent to participate.

Age

No age limit

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Ethics Committee Of Tabriz University Of Medical Sciences; Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code

Approval date

2016-01-06, 1394/10/16

Ethics committee reference number

TBZMED.REC.1394.861

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O14

ICD-10 code description

Gestational [pregnancy-induced] hypertension

Primary outcomes

1

Description

Added preeclampsia

Timepoint

During prenatal visits

Method of measurement

Manometer

Secondary outcomes

1

Description

Placental abruption

Timepoint

During pregnancy

Method of measurement

Physical examination

2

Description

Fetal death

Timepoint

During pregnancy

Method of measurement

Ultrasound

3

Description

Acute kidney injury

Timepoint

During pregnancy

Method of measurement

Physical examination

4

Description

Cerebral hemorrhage

Timepoint

During pregnancy

Method of measurement

Physical examination

Intervention groups

1

Description

methyldopa 250 mg b.i.d 4g/d

Category

Treatment - Drugs

2

Description

Hydralazine 5-10 mg iv every 20 min 30 mg

Category

Treatment - Drugs

3

Description

Nifedipine 10mg b.i.d

Category

Treatment - Drugs

4

Description

diltiazem 120-180 mg q.d

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Simin Taghavi

Street address

Alzahra Hospital; South Artesh Street; Bagh Shomal Crossroads

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology
University of Medical Sciences

Full name of responsible person

Dr. Alireza Rashidi

Street address

Golgasht Street; Central Building Number Two; third floor

City

Tabriz

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 and Technology 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Taghavi

Position

Professor of Obstetrics and Gynecology

Other areas of specialty/work

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Position

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Fax**Email**

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