Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 pressure10 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

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Simin Taghavi
Name of organization / entity
Tabriz University of Medical Sciences
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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
Nifidipine 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
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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