Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Labetalol versus Hydralazin in control of Hypertension in preeclamptic patients and the out come of their pregnancy

Protocol summary

Summary

Aim and object: Preeclampsia and Eclampsia is the reason for 25% of maternal mortality and it is the most common cause for maternal mortality in developing countries against with infections and bleeding. Due to this reason, this study was performed as a randomized clinical trial for purpose of studying influence of Labetalol versus Hydralazine in control of severe preeclampsia and the outcome of pregnancy in Kashan city, 2010.
Materials and methods: The study was performed on 190 patients with severe Preeclampsia or Eclampsia confiding to control blood pressure, The women with past history of arrhythmia (even due to hyperthyroidism), twin or high risk pregnancy(non cephalic presentation, history of uterine rupture, or previous caesarian section, fetal anomaly, previous still birth, thick meconiom) were excluded. The patients with a hypertension record of more than 160/105 mmHg, were divided to 2 groups each containing 95 members they were entered in one of two groups: Hydralazine group (H) or Labetalol group (L). In (L) group, the patients received 20mg intra venous injection(Iv) every 20 minutes then 40 mg and then 80 mg every 20 minutes if blood pressure was not controlled, and in (H) group they received 5mg Hyralazine every20 minutes by Iv injection if blood pressure was not controlled and if blood pressure did not reduced successfully the dose would be repeated. Blood pressure in patients were measured in sitting position by mercurial pressure gauge with suitable cuff in two groups every time 15 minutes after injection, and it was performed by 1 st degree resident from their right arms. The outcome of pregnancy containing of, the pathway of delivery (the obligatory caesarian sections), the APGAR score of the neonate at 1 st and 5 th and the need of admission in the ward or NICU in all patients in Hydralazine and Labetalol groups were controlled by accomplished by accustomed midwife and pediatrician. The average total dose and the average time of prescription in both groups were controlled as well The data was analyzed by spss version 14 soft ware and chi-square ,T test, Levene test, MannU-Whitney tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012185414N1**
Registration date: **2011-08-24, 1390/06/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-24, 1390/06/02

Registrant information

Name
Narges Oghbaei
Name of organization / entity
Kashan university of medical sciences
Country
Iran (Islamic Republic of)
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+98 36 1446 0180
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2009-04-20, 1388/01/31

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Labetalol versus Hydralazin in control of Hypertension in preeclamptic patients and the out come of their pregnancy

Public title
Comparison of Labetalol versus Hydralazin in control of Hypertension in preeclamptic patients and the out come of their pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Every pregnant woman by gestational age 20 to 42 weeks with a BP>160/105, singleton, estimated fetal weight < 4500 g Exclusion criteria: 1. History of basic chronic diseases ,including chronic HTN, hyperthyroidism, arrhythmia 2. Non cephalic presentation, macrosomia, thick meconium, previous history of caesarian section or uterine rupture which abdicate the option of NVD of patients. 3. History of long infertility, stillbirth, anomalous child, every reason for high risk pregnancy.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **190**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Science; Ethics committee
Street address
Pezeshk blvd, Ghotbe Ravandi blvd,
City
Kashan
Postal code
Approval date
2010-11-24, 1389/09/03
Ethics committee reference number
1873/1/8/29/پ

Health conditions studied

1

Description of health condition studied
preeclampsia
ICD-10 code
016-010
ICD-10 code description
ادم, پروتئینوری و اختلالات فشار خون در حاملگی, وضع حمل و نفاس

Primary outcomes

1

Description
Hydralazin effect on control of Hypertension
Timepoint
20minuts
Method of measurement
Mercurial Barometer

2

Description
Labetalol effect on control of Hypertension
Timepoint
20 minutes
Method of measurement
Mercurial Barometer

Secondary outcomes

1

Description
maternal pulse rate control
Timepoint
20minutes
Method of measurement
Maternal pulse rate control

2

Description
average decreased amount of systolic blood pressure after Hydralazin administration
Timepoint
20 minutes
Method of measurement
Mercurial Barometer

3

Description
average decreased amount of diastolic blood pressure after Hydralazin administration
Timepoint
20 minutes
Method of measurement
Mercurial Barometer

Intervention groups

1

Description
Hydralazin prescription in a 5 mg dose as first dose and blood pressure control after 20 minutes by first degree resident and repeat the same dose every 20 minutes up to 3 doses
Category
Treatment - Drugs

2

Description
Labetalol prescription in a 20 mg dose as first dose and blood pressure control after 20 minutes by first degree resident and repeat the complimentary doses as 40 mg and 80 mg every 20 minutes up to 3 doses
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shabihkhani hospital
Full name of responsible person
Dr.Zohre.Tabasi
Street address
Shabihkhani hospital, Beheshti avenue
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholamali Hammidi
Street address
Pezeshk blvd, Ghotbe Ravandi blvd
City
Kashan
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, Kashan 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
Kashan University of Medical Sience
Full name of responsible person
Dr.Zohreh Tabasi
Position
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Person responsible for updating data

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Position
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Other areas of specialty/work

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Postal code

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Fax

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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