Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effect of nonsteroidal anti-inflammatory drugs and acetaminophen on postpartum hypertension in patients with preeclampsia

Protocol summary

Study aim

Comparison of the effect of non-steroidal anti-inflammatory drugs and acetaminophen on postpartum hypertension in patients with preeclampsia, comparison of the time interval between delivery and the last blood pressure equal to and more than 110.160 mm Hg, comparison of mean mean arterial hypertension in postpartum patients To preeclampsia, compare the frequency of need for short-acting antihypertensive drugs to control sudden hypertension in patients with preeclampsia receiving nonsteroidal anti-inflammatory drugs and acetaminophen

Design

Clinical trial with control group, with parallel groups, double-blinded, randomized, phase 2 on 110 patients. Excel software rand function was used for randomization.

Settings and conduct

Obstetrics and Gynecology; Ayatollah Taleghani Hospital in Arak; According to the criteria of the American Society of Obstetrics and Gynecology Surgery, they are included in the study with one of two diagnoses of severe preeclampsia or preeclampsia added to chronic hypertension with severe symptoms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cesarean section candidates, age 18 to 35 years, no chronic liver-kidney disease and bleeding disorders, insensitivity to nonsteroidal anti-inflammatory drugs or acetaminophen; Exclusion criteria: increase in liver enzyme levels above 200 mg/dL, increase in serum creatinine levels above 2 mg/dL

Intervention groups

Diclofenac group: 24 hours after delivery, administration of 50 mg diclofenac suppository every 8 hours until the end of hospitalization Acetaminophen group: 24 hours after delivery, administered of 325 mg of acetaminophen suppository every 6 hours until the end of hospitalization

Main outcome variables

Pregnancy blood pressure control; Postpartum blood pressure control; Less use of antihypertensive drugs during and after pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052269N1**
Registration date: **2021-12-01, 1400/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**
Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Mahsa Dargahian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 6055

Email address

mooniaclinic@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of nonsteroidal anti-inflammatory drugs and acetaminophen on postpartum hypertension in patients with preeclampsia

Public title
The effect of anti-inflammatory drug and acetaminophen on postpartum hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cesarean candidate patients No chronic liver, kidney, hemorrhagic disorders No history of allergy to nonsteroidal anti-inflammatory drugs and acetaminophen Severe preeclampsia or preeclampsia added to chronic hypertension with severe symptoms
Exclusion criteria:
Increase in liver enzyme levels higher than 200 mg / dL Increase in serum creatinine higher than 2 mg / dL
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Random blocking with the size of random blocks (2, 4, 6) and randomization will be done using random sequence generation software, which in addition to simple randomization is able to generate random sequences by blocking method. We also use random allocation concealment, which is the method used to execute a random sequence on study participants so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences, in this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, principal investigator. The patient receives the drug (intervention or comparison group) in sealed packets that are coded. The coding is done by one of the project partners and the evaluator and the patient are blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۴۵
Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.ARAKMU.REC.1400.007

Health conditions studied

1

Description of health condition studied
Postpartum hypertension
ICD-10 code
O15.2
ICD-10 code description
Eclampsia in the puerperium

Primary outcomes

1

Description
Primary variable: Duration of high blood pressure
Timepoint
Measure blood pressure for 24 hours every hour and then every 4 hours
Method of measurement
Mercury sphygmomanometer

2

Description
Primary variable: Frequency of need to use short acting antihypertensive drugs
Timepoint
Measure blood pressure for 24 hours every hour and then every 4 hours
Method of measurement
Counting

Secondary outcomes

1

Description
Frequency of need to use short-acting antihypertensive drugs to control sudden hypertension in both groups receiving acetaminophen and nonsteroidal anti-inflammatory drugs
Timepoint
At the beginning of the study (before the intervention), for 24 hours every hour and then every 4 hours
Method of measurement
Counting

Intervention groups

1

Description
Intervention group 1: Mothers receiving acetaminophen 325 milligram suppository(Darupakhsh company) 24 hours after cesarean section every 6 hours until the end of hospitalization
Category
Treatment - Drugs

2

Description
Intervention group 2: Mothers receiving 50 milligram diclofenac suppository(Darupakhsh company) 24 hours after cesarean section every 6 hours until the end of hospitalization
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital in Arak
Full name of responsible person
Mahsa Dargahian
Street address
Taleghani Educational Medical Center; West side of Imam Khomeini Street next to the gas company
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Amir Almasi Hashiani
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Alam Al-Huda St., Shiroudi St.
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daneshkadeha@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mahsa Dargahian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable