Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effects of silymarin and N-acetylcysteine on improvement of, Hepatic and renal Abnormalities in Patients with SeverePreeclampsia in post-partum

Protocol summary

Study aim
Beneficial and therapeutic effects of silymarin and N-acetylcysteine(NAC) antioxidants on hepatic and renal impairment and hypertension in preeclampsia patients.

Design
Clinical trial without control group,with two parallel groups, two blind strains, randomized in a simple way

Settings and conduct
The medicines Provides the resident with the same packaging and coding before the study begins.One contains 70 mg of silymarin and the other contains 600 mg of NAC.In the maternity ward of Hajar hospital in Shahrekord, patient data and previous tests including blood pressure, liver tests and platelet count are extracted and recorded in relevant lists..Both patients receive routine preeclampsia treatment including magnesium sulfate and hydralazine.Medications in both intervention groups were administered orally and immediately and 12 and 24 hours after termination of pregnancy. AST, ALT, ALP.Billirubin total, direct,BUN, Cr and proteinuria and platelet counts were repeated 12, 36, and 60 hours after drug administration, respectively.At the end, the variables of the two groups are compared.

Participants/Inclusion and exclusion criteria
Conditions of entry of mothers between the ages of twenty and thirty with body mass index between twenty to twenty-four and gestational age of thirty-five to forty-two weeks with no history of abortion and pregnancy and blood pressure greater than 140/90 mmHg before termination of pregnancy and positive urine protein before termination of pregnancy.Exclusion criteria: history of hypertension and diabetes, renal disease, collagen and vascular diseases and cardiovascular disease, history of smoking, alcohol and maternal dissatisfaction

Intervention groups
One group received silymarin and the other group received NAC

Main outcome variables
serum liver enzymes; plt count;urea;creatinine; proteinuria;blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191231045965N1**
Registration date: **2020-03-08, 1398/12/18**
Registration timing: **prospective**

Last update: **2020-03-08, 1398/12/18**
Update count: **0**

Registration date
2020-03-08, 1398/12/18

Registrant information

Name
Sepideh Shabani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3335 4822

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sepide.shabaniii@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-19, 1398/12/29

Expected recruitment end date
2020-04-19, 1399/01/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effects of silymarin and N-acetylcysteine on improvement of, Hepatic and renal Abnormalities in Patients with SeverePreeclampsia in post-partum

Public title
Comparison the effects of silymarin and N-acetylcysteine on improvement of, Hepatic and renal Abnormalities in Patients with SeverePreeclampsia in post-partum
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Maternal age is between 20 and 30 years. mothers BMI is between 20 and 24. Gestational age at termination of pregnancy is between 35 and 42 weeks. The patient's blood pressure should be greater than 140/90 mmHg before termination of pregnancy. Proteinuria, in urine random sample before pregnancy termination. Lack of history of hypertension, diabetes, kidney disease, collagen vascular disease and other cardiovascular diseases. The mother is nulipar and has no previous abortion or pregnancy. No history of smoking or alcohol in the mother. Pregnancy is single and not molar. Indication of termination of pregnancy in a patient with severe preeclampsia. The patient has complete consent to participate in the study and has signed the consent form. No incidence of eclampsia prior to inclusion.
Exclusion criteria:
Patient dissatisfaction to participate in the study Patient with eclampsia
Age
From **20 years** old to **30 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
First, our patient cohorts are characterized by the size of the sample set.Then they are randomized by simple randomization using randomization software and generating randomized codes to assign each patient to each of the groups under study.The code generated by the software is specified by the sample size of each group and which code the disease belongs to the researcher.Patients were included in the initial cohort.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both medicines are packaged in the same package and given to the resident and she will provide the medication at the prescribed time
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Shahrekord University of Medical Sciences
Street address
No. 1,Godal cheshme Ave.,Gode pahlevanan Ave., Ayat Blvd., Shahrekord town
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815784653
Approval date
2019-11-05, 1398/08/14
Ethics committee reference number
IR.SKUMS.REC.1398.174

Health conditions studied

1

Description of health condition studied
Preeclampcia
ICD-10 code
O14.1
ICD-10 code description
Severe pre-eclampsia

Primary outcomes

1

Description
Liver enzymes
Timepoint
0,12,36 and 60 hours after intervention
Method of measurement
labratoary kit

2

Description

platlet count

Timepoint

0,12,36 and 60 hours after intervention

Method of measurement

count in mm3

3

Description

Proteinuria

Timepoint

0,12,36 and 60 hours after intervention

Method of measurement

labratoary kit

4

Description

urea

Timepoint

0,12,36 and 60 hours after intervention

Method of measurement

mg per dl

5

Description

Creatinine

Timepoint

0,12,36 and 60 hours after intervention

Method of measurement

mg per dl

6

Description

blood pressure

Timepoint

q 3 hours in study

Method of measurement

mmHg

Secondary outcomes

1

Description

number of blood pressure crisis in study

Timepoint

q 3 hours

Method of measurement

bp >160/110 mmhg

Intervention groups

1

Description

Intervention group: 70 mg silymarin is given immediately after delivery and 12 hours and 24 hours after delivery.

Category

Treatment - Drugs

2

Description

Intervention group: 600 mg of N-acetylcysteine is given immediately after delivery, 12 hours and 24 hours after delivery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Sepide Shabani

Street address

Nursery Street,Hajar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Mehraban Sadeghi

Street address

Vice chanceller for research,Building No.2,University headquarters,AyatollahKashani Blvd

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Leila Mahmoodnia
Position
Assistant Professor of Nephrology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available