

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.Bilirubin 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)

Phone

+98 38 3335 4822

Email address

sepide.shabaniiii@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**

Preeclampsia

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

labratory 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
labratory 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
City
Shahre-kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815784653
Phone
+98 38 3335 4822
Email
sepide.shabaniiii@gmail.com

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 chancellor for research,Building No.2,University headquarters,AyatollahKashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3334 2414
Email
kamal_solati@yahoo.co
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

Street address

Nursery Street, Hajar Hospital

City

Shahre-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Phone

+98 38 3222 0016

Email

leilamahmoodnia@yahoo.com

Person responsible for scientific 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

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Phone

+98 38 3222 0016

Email

leilamahmoodnia@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Sepide Shabani

Position

Internist Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Nursery Street, Hajar hospital

City

Shahre-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Phone

+98 38 3222 0016

Email

sepide.shabaniii@gmail.com

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