

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of silimaryn in improvement of hepatic and platlet damage in severe preeclampsia

Protocol summary

Summary

(1)Objectives: The objectives of this study is to evaluate the effect of silymarin on hepatic and platelet disorders in pregnant women with severe pre-eclampsia. (2)Design: this randomized double-blind study is to carry out on two groups of 30 women with severe preeclampsia. (3)Setting And Conducts:having entered the study, patients' data and previous testing including the blood pressure, liver tests and platelet count are to extract from their history and is recorded in related lists. Both groups of patients are to undergo routine treatment for severe pre-eclampsia, including magnesium sulfate and hydralazine. In the intervention group, 3 and 24 hours after the termination of pregnancy, 70 mg silymarin is to be administered orally. In the control group at the same times, placebo is to be administered. Liver enzymes, LDH uric acid , direct Bilirubin, Total Bilirubin, ALP, ALT, AST, Cr, BUN, and urinary proteinuria and platelet count is to be repeated 12 , 36 and 60 hours after drug administration. Finally, two groups are to be compared in terms of blood pressure, proteinuria, liver enzyme levels and platelet counts. (4)Participants: Inclusion criteria included termination of pregnancy due to severe preeclampsia, gestational age of 35 to 42 weeks at the time of pregnancy termination, absence of other diseases. (5)Intervention: Administration of 70 mg of silymarin in the intervention group and administration of placebo in the control group 3 and 24 hours after termination of pregnancy. (6)Main outcome measure:the number of platelets, AST, ALT, LDH

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090423887N1**

Registration date: **2015-11-10, 1394/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-10, 1394/08/19

Registrant information

Name

Fahime Kave baghbahadorani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 5751

Email address

kave@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University Of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of silimaryn in improvement of hepatic and platlet damage in severe preeclampsia

Public title

Evaluation the effect of silimaryn in improvement of hepatic and platlet damage in severe preeclampsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 and 30 years; BMI is to be 20 to 24; Gestational age is between 35 and 42 weeks at the time of termination of pregnancy; blood pressure before the termination of pregnancy is to be more than 90/140 mm Hg; The presence of Proteinuria in random urine samples before pregnancy termination; no history of hypertension, diabetes, kidney disease, Collagen vascular and other types of cardiovascular diseases; mother is supposed to be nulliparous; Singleton pregnancy not molar; termination of pregnancy is indicated By severe pre-eclampsia Exclusion criteria: presence of preeclampsia in mother

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University Of Medical Sciences

Street address

Shahrekord University Of Medical Sciences, Rahmatie,
Shahrekord, Iran

City

Shahrekord

Postal code

Approval date

2014-01-12, 1392/10/22

Ethics committee reference number

92-10-13

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

XV14

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

Primary outcomes

1

Description

platlet count

Timepoint

0,12,36 and 60 hours after intervention

Method of measurement

count in mm3

2

Description

blood pressure

Timepoint

q 3 hours in study

Method of measurement

mmHg

3

Description

liver enzyme

Timepoint

before and 12,36 and 60 hours after trial

Method of measurement

labratoary kit

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

In the intervention group, 3 and 24 hours after newborn birth, 70 mg of silymarin is to be orally administered to mother.

Category

Treatment - Drugs

2

Description

In the control group, 3 and 24 hours after birth, placebo is to be administered to the mother.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hajar Hospital

Full name of responsible person

Fahime Kaveh bagh bahadorani

Street address

Hajar Hospital, Parastar Street, Shahrekord, Iran

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University Of Medical Sciences

Full name of responsible person

Dr Mahmoud Rafiyan

Street address

Shahrekord University Of Medical Sciences, Rahmatie, Shahrekord, Iran

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord 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

Shahrekord University Of Medical Sciences

Full name of responsible person

Dr Sepide Miraj

Position

Atend

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University Of Medical Sciences

Full name of responsible person

Dr Sepide Miraj

Position

Obstetric And Gynecologist

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Person responsible for updating data

Contact

Name of organization / entity

Shahrekord Univrsity Of Medical Sciences

Full name of responsible person

Fahime Kave baghbahadorani

Position

Resident Of Gynecology

Other areas of specialty/work

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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