

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The therapeutic effect of Sildenafil Citrate on maternal and fetal outcomes of pregnancies associated with severe preeclampsia

Protocol summary

Study aim

Study of the therapeutic effect of Sildenafil Citrate on maternal and fetal outcomes of complicated pregnant women with severe preeclampsia

Design

A total of 64 single-pregnant women with severe preeclampsia indicating an expectant management and aging between 24 and 34 weeks were randomly and triple blind assigned to two groups of 1 and 2 treated with placebo and drug.

Settings and conduct

Patients with severe preeclampsia admitted to the maternity ward of Qaem Hospital in Mashhad who are eligible to enter the study are included. Individuals are randomly treated with medication and placebo through closed packets. So the therapist and patients and statistician do not know the type of drug they receive.

Participants/Inclusion and exclusion criteria

Pregnant women aged 18-50 years old with single pregnancy with a gestational age of 24 to 34 weeks who have been diagnosed with severe preeclampsia and who are candidate for expectant management, enrolled in the study. Exclusion criteria: History of chronic hypertension, chronic diseases such as diabetes; fetal malformations or maternal comorbiditis leading to early pregnancy termination; use of drugs such as erythromycin; israconazole; ketoconazole; antiretroviral compounds or any other drug It interferes with sildenafil; and drugs used to reduce blood pressure except methyl dopa.

Intervention groups

Sildenafil is given as an intervention to individuals and to Placebo with the same form and color is given to the other group.

Main outcome variables

Primary outcome: The mean pregnancy time from preeclampsia diagnosis to termination of pregnancy
Secondary outcomes: mean maternal blood pressure; the need for prescribing oral and intravenous antihypertensive drugs; examining the number of

sildenafil doses consumed from prescription to termination of pregnancy; maternal complications and fetal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190201042577N1**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

Azadeh Kamkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3611 1357

Email address

kamkara951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-19, 1397/10/29

Expected recruitment end date

2020-01-19, 1398/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The therapeutic effect of Sildenafil Citrate on maternal and fetal outcomes of pregnancies associated with severe preeclampsia

Public title
The therapeutic effect of Sildenafil Citrate on maternal and fetal outcomes of pregnancies associated with severe preeclampsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Pregnant women with single pregnancy with gestational age 24 to 34 weeks Ladies 18 to 50 years old Patients with the diagnosis of severe preeclampsia (systolic blood pressure greater than 160 and diastolic blood pressure greater than 110 in two times with a minimum measurement time of 4 hours and proteinuria greater than 300 mg in 24 hours) indicating an expected treatment.
Exclusion criteria:

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method, individual unit; using a packet packet

Blinding (investigator's opinion)
Triple blinded

Blinding description
Individuals entered into the study are randomly and triple blind divided into two groups by closed packets. The original drug and placebo were named by someone other than the therapist and researcher with the same shape and color as the first drug and the second drug, and each drug was given two groups. Data are analyzed by a statistician who is not aware of the type of medication.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

Street address

Ferdowsi University, Faculty of Medicine

City

mashhad

Province

Razavi Khorasan

Postal code

9177948964

Approval date

2019-01-11, 1397/10/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.582

Health conditions studied

1

Description of health condition studied

Severe Preeclampsia

ICD-10 code

O14.1

ICD-10 code description

Severe pre-eclampsia

Primary outcomes

1

Description

The mean of the pregnancy period since the diagnosis of severe preeclampsia until the end of pregnancy

Timepoint

since the diagnosis of severe preeclampsia until the end of pregnancy

Method of measurement

day

Secondary outcomes

1

Description

mean maternal blood pressure

Timepoint

Every four hours

Method of measurement

mercury Barometer

2

Description

newborn birth weight

Timepoint

at birth

Method of measurement

scaler

Intervention groups

1

Description

Intervention group: receive sildenafil tablets 25 mg every 8 hours.

Category

Treatment - Drugs

2

Description

Control group: receive a tablet of the same color and shape as the sildenafil tablet every 8 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Azadeh Kamkar

Street address

Ahmadabad Street, not reaching Shariati Square

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9919991766

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Kamkara951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqqodi

Street address

University of Mashhad University of Medical Sciences,
Faculty of Medicine, Mashhad University of Medical
Sciences, Mashhad

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Azadeh Kamkar

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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No. 406, Sayed Razi 48 Ave.

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Person responsible for scientific inquiries

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Full name of responsible person

Azadeh Kamkar

Position

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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