Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 eccept 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)

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+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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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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91735951
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Email
vcresearch@mums.ac.ir
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
Street address
No. 406, Sayed Razi 48 Ave.
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Person responsible for updating data

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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