

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of sildenafil citrate on fetal distress during labor and cesarean section - a double-blind clinical trial with placebo

Protocol summary

Study aim

Determining the effect and effectiveness of sildenafil citrate on fetal distress and the rate of cesarean section

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 104 patients. The online system was used for randomization.

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Settings and conduct

Pregnant mothers referred to Al-Zahra Hospital in Rasht divided into two groups of control and case, they are divided into equal numbers and randomly after entering the study, a test package is given to each participant in order numbered in order. The first dose of sildenafil or placebo is given when the participant enters the labor department for delivery. Sildenafil is given orally 50 mg every 6 hours for a maximum of 3 doses. The placebo is given to the control group according to the instructions.

Participants/Inclusion and exclusion criteria

Subjects include pregnant women referring to Alzahra Hospital in Rasht for normal delivery. Inclusion conditions: aged between 18-40 years, with singleton pregnancy (37-41 weeks), has a normal fetal structure, with cephalic presentation without any anomalies, estimated weight above 2500 grams or without CPD, who are candidate for normal vaginal delivery included in this survey. Exclusion criteria: drug reaction to Sildenafil, fetal anomalies, metabolic disorder, cardiac disorders, visual disorders, renal disorders, liver anomalies, previous cesarean, preeclampsia, HTN, Alcohol, Taking medications Nitrate, α -blocker.

Intervention groups

Intervention group: A group of 104 people who receive a package containing three capsules sildenafil 50 mg with instructions for clinical staff. Control group : A group of 104 people who receive a package containing three placebo capsules.

Main outcome variables

Need for cesarean section

General information

Reason for update

To enter the actual date of start and end of sampling

Acronym

Sildenafil citrate

IRCT registration information

IRCT registration number: **IRCT20100303003485N5**

Registration date: **2022-07-20, 1401/04/29**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **1**

Registration date

2022-07-20, 1401/04/29

Registrant information

Name

Forozan Milani

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1722 9328

Email address

milani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

2022-07-23, 1401/05/01

Actual recruitment end date

2022-09-23, 1401/07/01

Trial completion date

2022-09-23, 1401/07/01

Scientific title

The effect of sildenafil citrate on fetal distress during labor and cesarean section - a double-blind clinical trial with placebo

Public title

The effect of sildenafil citrate on cesarean section during labor

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-40 years Single pregnancy Term pregnancy (37-41 weeks) Normal fetal structure and without any anomalies Cephalic presentation Estimated weight above 2500 grams Without CPD Candidate for normal vaginal delivery

Exclusion criteria:

Drug reaction to Sildenafil Fetal anomalies Metabolic disorder Cardiac disorders Renal disorders Visual disorders Liver anomalies Previous cesarean Preeclampsia HTN Alcohol Taking medications Nitrate α -blocker

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **104**

Actual sample size reached: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

208 pregnant mothers referred to Al-Zahra Hospital in Rasht are randomly divided into 2 groups of 104 (intervention and control). Group 1 (intervention) is called A and group 2 (control) is called B. Random blocking will be done in such a way that numbers are assigned to the research units in order. Then there is a table with 47 rows called blocks and each block will have 4 parts and each part is named A and B, will be considered. In the next step, the numbers are placed in each house in order. After all the numbers are placed in the blocks, People who had a number in house A, Package with code A and people who had a number in house B, They will receive a package with code B. Concealment is done using the sealed envelope method. An online randomization service was used to generate the list.

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment group of each patient (The intervention group receiving sildenafil capsules and the control group receiving placebo capsules) will be determined only after randomization. This project will be carried out by a group of medical experts and all people will be blind (participants, Principal investigator, Health care personnel who are responsible for taking care of patients, Responsible for data collection, those who evaluate the outcome), Except for one specialist doctor who is independent from the research team, who prescribes the assigned codes for each of the pregnant mothers who refer to Al-Zahra Rasht Hospital. Also, each group of patients (intervention and control) will be treated in a separate place and are not related to each other.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, ShahidSiadati St., Namjoo Ave., Rasht, Guilan, IRAN

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.GUMS.REC.1401.114

Health conditions studied**1****Description of health condition studied**

Fetal distress in pregnancy

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Need for cesarean section

Timepoint

The first dose of sildenafil or placebo when the participant is in the active phase of labor. For delivery, she enters the labor department and is given. Sildenafil is given orally 50 mg every 8 hours for a maximum of 3 doses.

Method of measurement

The patient's blood pressure is measured every 15-30 minutes. Fetal heart rate is monitored.

Secondary outcomes

1

Description

Type of delivery

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

2

Description

Cesarean section indication

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

3

Description

Labor duration

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

4

Description

Abnormal bleeding during and after delivery

Timepoint

Until after delivery

Method of measurement

Will be recorded in the checklist.

5

Description

Meconium excretion

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

6

Description

Need for fetal blood sampling

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

7

Description

Fetal distress

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

8

Description

Birth weight

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

9

Description

Neonatal sex

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

10

Description

Apgar scores

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

11

Description

Umbilical artery pH

Timepoint

Until every stage of childbirth.

Method of measurement

Will be recorded in the checklist.

12

Description

Need for neonatal resuscitation

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

13

Description

Length of time in neonatal intensive care unit

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

14

Description

Seizures

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

15

Description

Neonatal encephalopathy

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

16

Description

Fetal and infant death

Timepoint

After delivery

Method of measurement

Will be recorded in the checklist.

Intervention groups

1

Description

Intervention group: a group of 104 people who received a package containing three oral capsules of sildenafil 50 mg brand Marham Darou (SDF), prepared by the pharmacy, up to a maximum of 3 doses every 6 hours. The first dose of sildenafil is given when the participant enters the labor ward for delivery (Spontaneous birth with dilatation of less than 4 cm, pregnant women who have cervical rip and induction has started for them and have effective contractions or induction of labor with oxytocin or rupture of the water sac) and the patient's blood pressure is measured every 15-30 minutes. Fetal heart rate monitoring is done and pregnancy care is ensured in both study groups.

Category

Prevention

2

Description

Control group: a group of 104 people who received a package containing three oral capsules of Mehram Daro brand prepared by the pharmacy, receive up to 3 doses

every 6 hours. The first placebo dose is given when the participant enters the labor ward for delivery (Spontaneous birth with dilatation of less than 4 cm, pregnant women who have cervical rip and induction has started for them and have effective contractions or induction of labor with oxytocin or rupture of the water sac) and the patient's blood pressure is measured every 15-30 minutes. Fetal heart rate monitoring is done and pregnancy care is ensured in both study groups.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr Forozan Milani

Street address

Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Email

Forozanmilani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

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research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Azadeh mahmoudi eisa abadi

Position

Resident of obstetric and gynecolog

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr Forozan Milani

Position

Gynecology and Obstetrics, perinatologist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Rasht University of Medical Sciences

Full name of responsible person

Sedighe Bab Eghbal

Position

MSc in Health Education

Latest degree

Master

Other areas of specialty/work

Health Promotion

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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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

There is still planning to share and publish.

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available

All interested in study.

Under which criteria data/document could be used

Not yet planned for it

From where data/document is obtainable

by Email

What processes are involved for a request to access

data/document

Not yet planned for it.

Comments