

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of sildenafil on fetal heart rate patterns during labor in primiparous pregnant women

Protocol summary

Study aim

Evaluation of the effect of sildenafil on fetal heart rate patterns during labor in primiparous pregnant women

Design

Clinical trial with control group; With Parallel groups; Single blinded; randomized; design of 200 patients

Settings and conduct

Eligible patients entering the study referred to Imam Sajjad Hospital of Yasuj University of Medical Sciences will be divided into two groups of 100 people and the fetal heart rate will be measured.

Participants/Inclusion and exclusion criteria

First and term pregnancy (gestational age over 37 weeks), Absence of pre-eclampsia, hypertension and gestational diabetes and absence of underlying disease in the mother, Not getting magnesium sulfate, Absence of fetal growth restriction, polyhydramnios and oligohydramnios of the fetus, Absence of prolonged rupture of membrane (more than 12 hours), singleton pregnancy Absence of structural abnormalities, Cephalic display, Candidate for vaginal delivery, Cervical dilatation less than 4 cm at the time of admission, candidate for induction

Intervention groups

Group A: In addition to induction and routine interventions during labor, they will receive oral sildenafil at a dose of 50 mg every 8 hours up to a maximum of 150 mg, the first dose of which is prescribed at the beginning of the study. Group B: Induction and routine interventions are performed.

Main outcome variables

Fetal heart rate patterns

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N19**

Registration date: **2024-02-27, 1402/12/08**

Registration timing: **prospective**

Last update: **2024-02-27, 1402/12/08**

Update count: **0**

Registration date

2024-02-27, 1402/12/08

Registrant information

Name

Fatemeh Bazarganipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-04, 1403/01/16

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sildenafil on fetal heart rate patterns during labor in primiparous pregnant women

Public title

Sildenafil and fetal heart rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
First and term pregnancy (gestational age over 37 weeks) Absence of pre-eclampsia, hypertension and gestational diabetes and absence of underlying disease in the mother Not getting magnesium sulfate Absence of fetal growth restriction, polyhydramnios and oligohydramnios of the fetus Absence of prolonged rupture of membrane (more than 12 hours) singleton pregnancy Absence of structural abnormalities Cephalic display Candidate for vaginal delivery Cervical dilatation less than 4 cm at the time of admission candidate for induction

Exclusion criteria:
Dissatisfaction of the mother

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. The random allocation sequence will be determined using the "computer Random generation" computer program. The sealed envelopes encoded and non-transparent (A,B) for the allocation of subjects to intervention (A) and control (B) groups will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
The blinding method is patients will not be aware of their allocation to study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town,

kohgiluyeh and boyer-ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.YUMS.REC.1402.037

Health conditions studied

1

Description of health condition studied

Fetal heart rate during labor

ICD-10 code

O76

ICD-10 code description

Abnormality in fetal heart rate and rhythm complicating labor and delivery

Primary outcomes

1

Description

Fetal heart rate patterns

Timepoint

Continuous fetal heart rate monitoring

Method of measurement

In this study, the normal fetal heart rate pattern based on the standard protocol means a heart rate between 110-160 beats per minute and a beat-to-beat variability of 5-25 beats per minute during labor and the pathological fetal heart rate pattern means a late deceleration in heart rate relative to to uterine contractions, early deceleration means a decrease in heart rate at the same time as uterine contractions, variable deceleration means a decrease in heart rate unrelated to uterine contractions, prolong deceleration means a deceleration in heart rate of more than 2 minutes in 10 minutes of continuous heart rate monitoring, tachycardia means a heart rate of more than 160 and bradycardia means a heart rate of less than 110 and reduced variability means changes of less than 5 beats per minute.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to induction and routine interventions during labor, they will receive oral sildenafil at a dose of 50 mg every 8 hours up to a maximum of

150 mg, the first dose of which is prescribed at the beginning of the study.

Category

Treatment - Drugs

2

Description

Control group: Induction and routine interventions are performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasuj University of Medical Sciences

Full name of responsible person

Zahra Asadi

Street address

No. 7916839319, Emam Sajad Hospital, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 917 793 1581

Email

zasadik66@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Amin Hosseini

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

amin.hosseini@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Zahra Asadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

City

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Province

Kohgiluyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 917 793 1581

Email

zasadik66@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Zahra Asadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Province
Kohgiluyeh-va-Boyerahmad
Postal code
7916839319
Phone
+98 917 793 1581
Email
zasadik66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Zahra Asadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town,
Kohgiluyeh and Boyer-Ahmad
City
Yasuj

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available