

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison The effect of sildenafil citrate consumption on the improvement of amniotic fluid index in oligohydraminos patients and placebo group(control)

Protocol summary

Study aim

effect of sildenafil citrate on improving the amniotic fluid index in oligohydramnios patients referred to Hamadan Fatemieh Hospital.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 42 patients. A table of numbers is used for randomization.

Settings and conduct

The effect of Sildenafil Citrate in improving the amniotic fluid index in oligohydramnios patients - in Hamadan Fatemieh Hospital - In the intervention group (Sildenafil Citrate with a dose of 50 mg three times a day is prescribed to the patient along with receiving 3 liters of intravenous fluid and every week to two weeks amniotic fluid is evaluated by ultrasound). The method was double-blind (patient and sonologist). None of these people were aware of their division into intervention and control groups.

Participants/Inclusion and exclusion criteria

Include all pregnant women with an age range between 15-50 years and a gestational age of 24-36 weeks and an amniotic fluid index below 8. All patients with preeclampsia, history of taking blood pressure lowering drugs, and patients with sildenafil allergy will be excluded from this study.

Intervention groups

In the intervention group (Sildenafil Citrate with a dose of 50 mg three times a day is prescribed to the patient along with receiving 3 liters of intravenous fluid and every week to two weeks amniotic fluid is evaluated by ultrasound). In the control group (internally, it is prescribed to the patient three times a day along with receiving 3 liters of intravenous fluid and every week to two weeks amniotic fluid is evaluated by ultrasound).

Main outcome variables

Amniotic fluid index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055868N1**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

leila torkashvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 7013

Email address

l.torkashvand23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison The effect of sildenafil citrate consumption on the improvement of amniotic fluid index in oligohydraminos patients and placebo group(control)

Public title

The effect of sildenafil citrate in oligohydramnios patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All pregnant women Age range between 15-50 years Gestational age 24-36 weeks The amniotic fluid index is below 8

Exclusion criteria:

Patients with preeclampsia History of taking antihypertensive drugs Patients with sildenafil allergy

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Quadruple block method and table of random numbers were used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the sonologist who evaluate the test results blindly. In this way, none of the patients and the sonologist are aware of the grouping of the patients in the placebo group and the main drug group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ibn- Sina University of Medical Sciences, Hamadan

Street address

Department of Ethics in Medicine., Ibn-Sina University of Medical Sciences., Shahid fahmideh St

City

Hamedan

Province

Hamadan

Postal code

6517838736

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.UMSHA.REC.1401.361

Health conditions studied

1

Description of health condition studied

Oligohydroaminos

ICD-10 code

O41.0

ICD-10 code description

Oligohydramnios

Primary outcomes

1

Description

Amniotic fluid index

Timepoint

Every week to two weeks

Method of measurement

Abdominal sonography

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" sildenafil citrate tablets manufactured by Pharmachemy Company are prescribed to the patient orally at a dose of 50 mg every 8 hours for two weeks.

Category

Treatment - Drugs

2

Description

"Control group:" Placebo pills are prescribed every 8 hours for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyeh hospital in Hamedan

Full name of responsible person

Shahla Nasrolahi

Street address

Fatemiyeh Hospital., Pasdaran St

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6517789971

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Hp.fatemieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

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Hamedan University of Medical Sciences., Shahid Fahmideh St.

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Fax**Email**

Info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Leila Torkashvand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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