Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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Hamedan

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Hamadan

Postal code
6517789971

Phone
+98 81 3834 0266

Email
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

Street address
Hamedan University of Medical Sciences., Shahid Fahmideh St.

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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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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