

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the effects of sildenafil on oligohydramnios in pregnant women.

Protocol summary

Study aim

Evaluation of the effects of sildenafil on amniotic fluid index in cases of oligohydramnios.

Design

190 eligible pregnant women are randomly assigned into the two groups of intervention and control groups.

Settings and conduct

Triple blind clinical trial in Akbarabadi Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Singleton pregnancy and gestational age of 30-37 weeks and amniotic fluid index (AFI) less than 5 cm which is discovered during third-trimester ultrasonography. The women with abnormal fetal Doppler, fetal anomalies, fetal growth restriction, fetal distress like nonreactive non stress test (NST), maternal chronic hypertension, pre-gestational diabetes, active labor, rupture of membranes, treatment with prostaglandin synthase inhibitors, maternal diseases contraindicating bolus fluid therapy (kidney, lung, or heart disease) are excluded from the study.

Intervention groups

Intervention group will receive sildenafil (25 milligram every 8 hours) plus 2 liter intravenous hydration (250 milliliter/ hour every 4 hours isotonic solution) and control group will receive placebo plus 2 liter intravenous hydration (250 milliliter/ hour every 4 hours isotonic solution).

Main outcome variables

Main outcome is increasing in amniotic fluid index at 6 weeks of intervention or before delivery, whichever occurred first.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091023002624N21**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **prospective**

Last update: **2017-12-17, 1396/09/26**

Update count: **0**

Registration date

2017-12-17, 1396/09/26

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of sildenafil on oligohydramnios in pregnant women.

Public title

The effects of sildenafil on oligohydramnios

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent Singleton pregnancy Gestational age 30-37 weeks Amniotic fluid index (AFI) less than 5 cm which was discovered during third-trimester ultrasonography

Exclusion criteria:
Abnormal fetal Doppler Fetal anomalies Fetal growth restriction Fetal distress like nonreactive non stress test (NST) Maternal chronic hypertension Pre-gestational diabetes, Active labor Rupture of membranes Treatment with prostaglandin synthase inhibitors Maternal diseases contraindicating bolus fluid therapy (kidney, lung, or heart disease)

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **190**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization using sealed envelopes.

Blinding (investigator's opinion)
Triple blinded

Blinding description
participants, principle investigator, investigator and midwives who care for participants during the trial, and data analyser are blinded to the study group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemmat Highway, Chamran Cross

City

Tehran

Province
Tehran

Postal code
1449614535

Approval date
2017-11-13, 1396/08/22

Ethics committee reference number
IR.IUMS.REC 1396.31246

Health conditions studied

1

Description of health condition studied

Oligohydramnios

ICD-10 code

O41.0

ICD-10 code description

Oligohydramnios

Primary outcomes

1

Description

increasing in amniotic fluid index

Timepoint

at 6 weeks of intervention or before delivery, whichever occurs first.

Method of measurement

ultrasonogram

Secondary outcomes

1

Description

gestational age at delivery

Timepoint

Delivery

Method of measurement

Data sheets

2

Description

route of delivery

Timepoint

Delivery

Method of measurement

Data sheets

3

Description

Neonatal weight

Timepoint

At birth

Method of measurement

Data sheets, gram

4

Description

Neonatal Apgar score

Timepoint

At 1 and 5 minutes after birth

Method of measurement

Data sheets

5

Description

Umbilical artery pH

Timepoint

at birth

Method of measurement

Data sheets

6

Description

Admission to NICU

Timepoint

any time after birth

Method of measurement

Data sheets

7

Description

Length of NICU stay

Timepoint

After discharge

Method of measurement

Data sheets, Days

Intervention groups

1

Description

Intervention group: sildenafil (25 milligram every 8 hours) plus 2 liter intravenous hydration(250 milliliter/ hour every 4 hours isotonic solution) will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: control group will receive placebo plus 2 liter intravenous hydration(250 milliliter/ hour every 4 hours isotonic solution).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi Street, Molavi Cross.

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۳۵۱۴

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakooti

Street address

Hemmat Highway, Chamran Cross.

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

50

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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Molavi Street, Molavi Cross.
City
Tehran
Province
Tehran
Postal code
۱۱۶۸۷۴۳۵۱۴
Phone
+98 21 5563 3244
Email
maryamkashanian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Kashanian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Molavi Street, Molavi Cross.
City
Tehran
Province
Tehran
Postal code
۱۱۶۸۷۴۳۵۱۴
Phone
+98 21 5563 3244
Email
maryamkashanian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Maryam Kashanian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Molavi street, Molavi Cross.
City
Tehran
Province
Tehran
Postal code
۱۱۶۸۷۴۳۵۱۴
Phone
+98 21 5563 3244
Email
maryamkashanian@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Presenting at a paper, congress or seminars.

When the data will become available and for how long

After finishing the study.

To whom data/document is available

Iran University of Medical Sciences.

Under which criteria data/document could be used

Permission from Iran University of Medical Sciences.

From where data/document is obtainable

From Iran University of Medical Sciences.

What processes are involved for a request to access data/document

Request from Iran University of Medical Sciences.

Comments