Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

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

Protocol summary

Study aim
Evaluation of the effects of sildenaphil on amniotic fluid index in cases of oligohydramnios.
Design
190 eligible pregnant women are randomly assigned into the two groups oof 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 discoveredduring 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 sildenaphil on oligohydramnios in pregnant women.

Public title
The effects of sildenaphil 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 discoveredduring 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 envelops.

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

rout 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
۱۱۶۸۷۴۳۵۱۴
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
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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
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Molavi street, Molavi Cross.
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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