Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effectiveness of sildenafil plus hydration therapy with the hydration therapy alone on the treatment of oligohydramnios in pregnant women referring to Arash Hospital

Protocol summary

Study aim

The aim of this study was to evaluate the effect of sildenafil on the treatment of oligohydamnios.

Design

This study will be conducted on 52 eligible women with oligohydramnios who have a gestational age greater than 28 weeks. The participants will be randomly divided into two groups of intervention and control.

Settings and conduct

This is a randomized clinical trial that will be conducted on pregnant women with oligohydramnios at 28 weeks of gestation referred to Arash Hospital. After random allocation, patients will be assigned to control or interventional groups. After being admitted, each patient will receive 2 liters of ringer serum for 24 hours. After 24hr of hydration, AFI will be checked by ultrasound and patients who show at least a 20% improvement in AFI will be discharged from the hospital. After discharge, the intervention group will use 2 liters of water per day plus 25 mg oral sildenafil 3 times a day for 6 weeks. The control group will receive only 2 liters of water per day at the same time. We will perform 2 times a week NST, weekly sonography, and biophysical profile test and will advise mothers to have more rest and count the fetal movements.

Participants/Inclusion and exclusion criteria

Participants should have a singleton pregnancy, gestational age 28 weeks or more, an amniotic fluid index less than 8 centimeters. patients with IUGR, abnormal Doppler or NST, prostaglandin synthase inhibitors treatment, rupture of membranes, active labor, chronic blood pressure, diabetes mellitus and hydration therapy contraindications will be excluded.

Intervention groups

Intervention group: sildenafil plus hydration therapy
Control group: only hydration therapy

Main outcome variables

Primary outcome: Amniotic fluid index Secondary outcome: type of delivery; gestational age at delivery; duration of intervention until delivery; fetal weight, APGAR Score, NICU admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170917036227N3**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-15, 1397/04/24**
Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

mvahid@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of sildenafil plus hydration therapy with the hydration therapy alone on the treatment of oligohydramnios in pregnant women referring to Arash Hospital

Public title
Effect of sildenafil on treatment of oligohydramnios
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
singleton pregnancy Gestational age 28 weeks and above Ultrasonically diagnosed oligohydramnios in the third trimester (defined as Amniotic Fluid Index (AFI) blow 8 cm)
Exclusion criteria:
Intrauterine growth restriction (IUGR) Fetal Anomaly Abnormal Blood Flow Patterns by Color Doppler flow imaging Abnormal NST Treatment with Prostaglandin synthetase inhibitors Rupture of membranes Active Labor Chronic Hypertension Overt Diabetes Mellitus Maternal Hydration therapy contraindications (like renal, respiratory or cardiac diseases)
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The considered sample size is 52, with 26 people in each group. Block randomization method was designed by the group's epidemiologist using Stata version 13 software. The size of blocks considered is 6. The random allocation list for patients is solely available to the epidemiologist. To hide the random allocation process, 52 card sequences of treatments will be written accordingly, and then the cards will be placed inside sealed envelopes. A 10-digit random code will be written on each packet as the patient's identification number. When the physician announces the eligibility of a patient, the methodologist will provide the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
the statistical analyser will be unaware of the type of intervention performed in the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical sciences
Street address
Qods st, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-08-06, 1396/05/15
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3070

Health conditions studied

1

Description of health condition studied
Oligohydramnios
ICD-10 code
O41.0
ICD-10 code description
Oligohydramnios

Primary outcomes

1

Description
Amniotic fluid index
Timepoint
24 hours after starting treatment and every week after discharge for up to 6 weeks
Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Duration of intervention until delivery
Timepoint
During intervention
Method of measurement
check list

2

Description
Infant weight
Timepoint
At the end of the study
Method of measurement
Balance (in kilograms and grams)

3

Description
NICU Admission
Timepoint
At the end of the study
Method of measurement
File information

4

Description
APGAR Score
Timepoint
At the end of the study
Method of measurement
File information

5

Description
Type of delivery
Timepoint
At the end of the study
Method of measurement
File information

6

Description
Gestational Age at birth
Timepoint
At the end of the study
Method of measurement
File information

Intervention groups

1

Description
Intervention group: oral sildenafil tablets with a dose of 25 mg every 8 hours along with hydration therapy
Category
Treatment - Drugs

2

Description
Control group: Hydration therapy alone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's Hospital
Full name of responsible person
Dr Mahbobeh Mesgaran
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Arash Wamen's Hospital
Full name of responsible person
Dr Mahbobeh Mesgaran
Position
Resident
Latest degree
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Person responsible for scientific inquiries

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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