Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Sildenafil on the clinical course of newborns with transient tachypnea of newborns, A Clinical Trial

Protocol summary

Study aim

Evaluation the effect of Sildenafil on the clinical course of newborns with transient tachypnea of newborns.

Design

This study was a double-blind, placebo-controlled trial in which 80 neonates with gestational age of 34 to 41 weeks of gestational age were diagnosed with TTN, 40 of them in the intervention group and 40 in the control group. Due to the lack of a similar study in the past, 20 neonates were entered into a pilot and based on their results, the sample size was calculated.

Settings and conduct

A study was conducted in Ahvaz Imam Khomeini Hospital's Neonatal Department. Correction was designed to reduce the likelihood of information bias, both patients and the assessor and the person analyzing the treatment outcomes, the type of treatment assigned to each individual, and Which group of patients were kept unaware.

Participants/Inclusion and exclusion criteria

Infants born at the gestational age of 34 weeks to 41 weeks of gestation and diagnosed with TTN were included in the study. Neonates with meconium aspiration, respiratory distress syndrome, pneumonia and congenital heart disease, toxic hypoxia, persistent hypoglycemia and polycythemia, Congenital anomaly, proven systemic infection (positive blood culture), intrauterine growth retardation, and history of fetal distress, multiple organ failure (MODS) were eliminated.

Intervention groups

The newborns were randomly assigned into two groups receiving sildenafil and placebo (5% dextrose). In the intervention group, sildenafil was given as mg / kg 1 every 8 hours with a gavage tube, the first dose was administered immediately after admission. In the second group, placebo was prescribed. Sildenafil was prepared as a white powder in 5% dextrose at a concentration of 1 mg / ml. Both sildenafil solution in dextrose and placebo were stained in vials of the same form.

Main outcome variables

Need for mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161206031269N2**
Registration date: **2018-09-03, 1397/06/12**
Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**
Update count: **0**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Azin Khalafiniya

Name of organization / entity

Jundishapur University of Ahvaz

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

empty

Scientific title

Effect of Sildenafil on the clinical course of newborns with transient tachypnea of newborns, A Clinical Trial

Public title

Effect of Sildenafil on the clinical course of newborns with transient tachypnea of newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns with transient tachypnea of newborns

Exclusion criteria:

Moconia aspiration Raspiratory distress syndrom Pneumonia Congenital heart disease Sustained hypoglycemia Polycytemia Congenital anomaly Proven systemic infection Intrauterine growth retardation Fetal distress Multiple organ dysfunction score Poisonous hypoxia

Age

From **238 days** old to **287 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The newborns were randomly assigned into two groups receiving sildenafil and placebo (5% dextrose). In the intervention group, 40 sildenafil infants received 1 mg / kg every 8 hours with a gavage tube, the first dose was administered immediately after admission. In the second group, 40 newborns were given placebo. Physicians and nurses responsible for treating the contents of the vials were unaware.

Blinding (investigator's opinion)

Double blinded

Blinding description

To reduce the risk of bias, patients and assessor and statistician were blinded to know the type of treatment assigned to reach person and that which patient was in which group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی جندی شاپور اهواز

Street address

Gileston st. , Jundishapour University of Medical Sciences, vice chancellor for Research and Technology

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Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.AJUMS.REC.1397.249

Health conditions studied

1

Description of health condition studied

Newborns with transient tachypnea of newborns

ICD-10 code

Q20

ICD-10 code description

Transient tachypnea of newborns (TTN)

Primary outcomes

1

Description

The need for mechanical ventilation

Timepoint

Start of intervention and discharge time

Method of measurement

Based on clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, sildenafil was given as mg / kg 1 every 8 hours with a gavage tube, the first dose was administered immediately after admission.

Category

Treatment - Drugs

2

Description
Control group: In this group, placebo (dextrose 5%) was gavaged every 8 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neonatal Department of Imam Khomeini Hospital, Ahvaz
Full name of responsible person
Dr. Masoud Dehdashtian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
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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