

# 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)

##### Phone

+98 61 4253 3449

##### Email address

khalafiniya.a@ajums.ac.ir

##### 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 Respiratory 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

##### City

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

##### Street address

Azadegan Avenue

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673111

##### Phone

+98 61 2223 2292

##### Email

dehdashtian@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Hatam Boustani

##### Street address

golestan Ave.

##### City

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##### Province

Khouzestan

##### Postal code

39345-61355

##### Phone

+98 61 3333 7077

##### Email

info@ajums.ac.ir

##### 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Masoud Dehdashtian

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

##### Street address

Imam Khomeini Hospital, Ahvaz , Azadegan Avenue

##### City

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##### Province

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

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##### Position

Assistant Professor

##### Latest degree

Subspecialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Dehdashtian

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Email**

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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