

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the Effect of Sildenafil on Improving Chronic Lung Disease of neonates

Protocol summary

Study aim

evaluation of the therapeutic effect of sildenafil in neonates with chronic lung disease Comparison of oxygen demand in sildenafil patients and controls Comparison of hospital stay, pulmonary pressure and Systemic Blood Pressure Changes in sildenafil patients and controls

Design

randomized clinical trial with parallel Controlled group, single-blind

Settings and conduct

Approximately 40 patients (those referred to Al-Zahra Hospital with a diagnosis of chronic lung disease in one year) will enter the study in accordance with the entry and exit criteria. Patients will be divided into control and study groups using Randomiser.org. All patients will receive routine and necessary measures, and after obtaining written consent from the parents to participate in the study, and confirmation of increased pulmonary pressure by echocardiography performed by a pediatric cardiologist, sildenafil tablets in the intervention group and placebo It will start as a form of control in the control group for patients, and parents will not know about the drug or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Chronic lung disease based on the need for oxygen at 36 weeks of gestation Neonatal hemodynamic stability Lack of gastrointestinal disorders Written consent of the patient's parents to participate in the study Output Criteria: Need oxygen at 36 weeks of intrauterine age for known causes other than -Nutritional intolerance

Intervention groups

Intervention group: Sildenafil 50 mg tablets of Obaidi company with a dose of 2 mg per kilogram of body weight will be given to infants orally every 8 hours. Control group: The placebo will start as a single form and one color with the same characteristics of sildenafil tablets for patients.

Main outcome variables

Arterial oxygen saturation control Reduction of hospital stay Systemic blood pressure control Pulmonary blood pressure control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160102025811N4**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **retrospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Mirhadi Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

drmussaviahadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of Sildenafil on Improving Chronic Lung Disease of neonates

Public title

Sildenafil on Improving Chronic Lung Disease of neonates

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic pulmonary disease based on oxygen demand in 36 weeks of intrauterine age Infant hemodynamic stability Absence of gastrointestinal disorders Written consent of the patient's parents to participate in the study

Exclusion criteria:

Parents 'dissatisfaction with patients' participation in the study The need for oxygen during the 36 weeks of intrauterine age is known due to chronic lung disease Hemodynamic instability Nutritional intolerance

Age

To 28 days old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 40

More than 1 sample in each individual

Number of samples in each individual: 2

Referred to Alzahra Hospital with Chronic Pulmonary Disease

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random allocation software: Random allocation software. So that all patients who were hospitalized in Al-Zahra Medical Center in Tabriz in 1398 and 1399 with the diagnosis of chronic lung disease and had entry criteria and no exit criteria, will enter the study. Using the software, they will be divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients will undergo routine measures such as respiratory support and oxygen therapy, and after obtaining written consent from parents to participate in the study, sildenafil 50 mg overdose tablets at a dose of 2 mg per Kg of body weight will be started every 8 hours in the intervention and placebo tablets in the same color form as patients with the same characteristics in the control group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Ethics Committee of Tabriz University of Medical Sciences

Street address

GOLGASHT Ave, Faculty of Medicine

City

Tabriz

Province

East Azarbaijan

Postal code

5154751637

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.TBZMED.REC.1398.488

Health conditions studied**1****Description of health condition studied**

Chronic lung disease of newborns

ICD-10 code

P00.3

ICD-10 code description

Newborn (suspected to be) affected by other maternal circulatory and respiratory diseases

Primary outcomes**1****Description**

Fio2

Timepoint

daily

Method of measurement

Oxymetric pulse and heart monitoring

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Sildenafil 50 mg tablets from Obidi

Company with a dose of 2 mg per kg body weight will be fed to infants every 8 hours.

Category

Treatment - Drugs

2**Description**

Control group: The placebo will be given to babies in the same shape and color as Sildenafil.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Mir Hadi Musavi

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Sheshgalan Street, Children's Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hasan Soleimanpour

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

MirHadi Mousavi

Position

Assistant Prof.

Latest degree

Subspecialist

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

Hematology

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Phone

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