

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of effectiveness of surfactant administration via endotracheal tube and thin endotracheal catheter in neonates with respiratory distress syndrom

Protocol summary

Summary

The aim of this study was to determine and compare effectiveness of surfactant administration via endotracheal tube and thin endotracheal catheter in neonates with respiratory distress. This study is a single-blind, double-blind, clinical trial. 105 patients with acute respiratory distress referring to the Shahrekord Neonatal ward with Inclusion criteria: RDS clinical symptoms include respiratory distress; tachypnea. Exclusion criteria: major anomalies; mother curioamniotic history; early sepsis; need to continue mechanical ventilation immediately after injection of surfactant. They are randomly selected. Patients with respiratory distress are divided into two groups of 52 people. The first group is injected by intraperitoneal intubation with rutin injection and in the second group, the injection of surfactant is performed using endotracheal tube (vascular tube). Patients are checked up to twenty-eight days later. The need for oxygen and the administration of surfactant respond to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102110222N16**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of surfactant administration via endotracheal tube and thin endotracheal catheter in neonates with respiratory distress syndrom

Public title

Comparison of effectiveness of surfactant administration via endotracheal tube and thin endotracheal catheter in neonates with respiratory distress.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: RDS clinical symptoms include respiratory distress; tachypnea. Exclusion criteria: major anomalies; mother curioamniotic history; early sepsis;

need to continue mechanical ventilation immediately after injection of surfactant.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani street

City

Shahrekord

Postal code**Approval date**

2016-07-03, 1395/04/13

Ethics committee reference number

IR.SKUMS.REC.1395.69

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

Acute Respiratory Distress

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

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

Frequency of administration of surfactant

Timepoint

Twenty eight later

Method of measurement

checklist

Secondary outcomes**1****Description**

Duration of oxygen demand

Timepoint

Twenty eight day later

Method of measurement

checklist

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

The first group is injected by intraperitoneal intubation with routin injection

Category

Treatment - Drugs

2**Description**

The second group, the injection of surfactant is performed using endotracheal tube (vascular tube)

Category

Treatment - Drugs

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

Hajar Hospital in Shahrekord

Full name of responsible person

Roya Choopani

Street address

Parastar street, Hajar Hospital of Shahrekord University of Medical Sciences

City

Shahrekord

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

Vice chancellor for research, Shahrekord University of Medical Science

Full name of responsible person

Dr. Kamal Solati

Street address

Kashani street, shahrekord University of Medical Sciences

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahrekord University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Roya Choopani

Position

Pediatrician, Assistant professor

Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty