Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 routin 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

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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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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