Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparison of surfactant injection through tracheal in neonates with respiratory distress syndrome

Protocol summary

Summary

Objective: to determine therapeutic effect of surfactant injection through tracheal in hospitalized newborn infants with respiratory distress syndrome in Amiralmomenin hospital in Semnan. Study design: non-randomized, Parallel-group, and without placebo. single-center. Inclusion criteria: premature infants admitted to the neonatal intensive care unit with a definite diagnosis of respiratory distress syndrome, age ≤ 24 hours. Exclusion criteria: infants with major abnormalities, chromosomal abnormalities, severe asphyxia, need to intubation at birth. Statistical population: all newborns with respiratory distress syndrome. Method of execution: surfactants administration via endotracheal tube. Clinical Guide of surfactants administration will be accordance to Aguar and colleagues study in 2014. Data collecting tool: 1. gestational age, gender, singleton or multiple pregnancy, maternal risk factors, birth weight, birth length and head circumference at birth, method of delivery, one and five-minute Apgar birth number, receiving cortons before birth by mothers and analysis of blood gases arterial at first hour of birth 2. Check list of data records based on RDS score, intensity of respiratory distress based on the X-ray, neonatal mechanical ventilation, surfactant dosage, age of prescribed surfactant (h), length of stay, patient outcomes (death / improvement) , Complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080825732N8**
Registration date: **2017-01-16, 1395/10/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-16, 1395/10/27

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

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Recruitment status
Recruitment complete

Funding source
Semnan University of Medical Sciences

Expected recruitment start date
2016-03-20, 1395/01/01

Expected recruitment end date
2017-03-19, 1395/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparison of surfactant injection through tracheal in neonates with respiratory distress syndrome

Public title
comparison of therapeutic effect of surfactant injection through tracheal in neonates with respiratory distress syndrome hospitalized in Amir al-momenin Hospital in Semnan

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria: premature infants admitted to the neonatal intensive care unit with definitive diagnosis of RDS by pediatrician using clinical symtoms including tachypnea, intercostal retraction, nasal flaring, cyanosis, and hypotension and respiratory arrest. Exclusion criteria: infants with major abnormalities, chromosomal abnormalities, severe asphyxia, and need to Antvbyshn at birth.

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences, Deputy of research and technology, Ethics Committee

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Postal code

3514799442

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

IR.SEMUMS.REC.1395.14

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Severity of respiratory distress

Timepoint

Before starting study and one hour after Following Prescribing Dosing surfactant

Method of measurement

Based on radiography

2

Description

Apgar score

Timepoint

minute one and five Birth

Method of measurement

View Information registered records Filed in the labor

Secondary outcomes

1

Description

Severity of respiratory distress

Timepoint

After injecting surfactant

Method of measurement

Based on Picture Radiography

Intervention groups

1

Description

Intervention group: Surfactant injection (Prescribed according to the instructions the manufacturer and section stock) to method of INSURE for all neonates with respiratory distress syndrome (RDS) hospitalized in the neonatal intensive care unit Amiralmomenin hospital, Semnan.

Category

Treatment - Drugs

2

Description

In control group, no intervention was performed and were assessed only for comparison of two groups of the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital AmirAlMomenin Semnan

Full name of responsible person
Dr Shamsollah Noripour

Street address
Hospital AmirAlMomenin, Mostafa Khomeini Blvd, Semnan

City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences, Vice Chancellor for Research and Technology

Full name of responsible person
Dr Mohammadreza Asgari

Street address
Semnan University of Medical Sciences, Deputy of Research and Technology, Basij Blvd, Semnan

City
Semnan

Grant name

Grant code / Reference number

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

Title of funding source
Semnan University of Medical Sciences, Vice Chancellor for Research and Technology

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
Semnan University of Medical Sciences

Full name of responsible person
Dr Shamsollah Nouripour

Position
Pediatrician

Other areas of specialty/work

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Person responsible for scientific inquiries

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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