

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

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

Protocol summary

2017-01-16, 1395/10/27

Summary

Objective: to determine therapeutic effect of surfactant injection through tracheal in hospitalized newborn infants with respiratory distress syndrome in Amiral-momenin 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 \leq 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.

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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Iran (Islamic Republic of)

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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

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

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 symptoms 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 Antvbysn 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 Amiralmomentin 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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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