Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

A randomized trial comparing surfactant administration using InSurE technique and the minimally invasive surfactant therapy in preterm infants at the age of 28 to 36 weeks of gestation and respiratory distress syndrome

Protocol summary

Study aim
A randomized trial comparing surfactant administration using InSurE technique and the minimally invasive surfactant therapy in preterm infants at the age of 28 to 36 weeks of gestation and respiratory distress syndrome

Design
A clinical trial with a control group with a parallel group design, single blind; randomized; Phase 2-3, on 112 patients. Block randomization method for randomization.

Settings and conduct
1- Study place:This study will be performed in the neonatal intensive care unit of Fatemieh Hospital in Hamadan. 2-Blinding: The person evaluating the outcome will be unaware of the type of intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age of 28-37 weeks; respiratory distress syndrome; fraction of inspired oxygen>40 require; treatment with surfactant in less than 24 hours after birth. Non-inclusion: Suffering of congenital heart abnormalities; APGAR score<5; suffering from any congenital disease.

Intervention groups
Intervention group 1:56 participants take 200 mg/kg surfactant by MIST method Intervention group 2: It receives the same amount of surfactant by ENSURE method.

Main outcome variables
Need to respiratory support and ventilation within a week; hospital stay; mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N8**
Registration date: **2021-01-22, 1399/11/03**
Registration timing: **retrospective**

Last update: **2021-01-22, 1399/11/03**
Update count: **0**

Registration date
2021-01-22, 1399/11/03

Registrant information

Name
Mohammad Faryadras

Name of organization / entity
Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 3428 9706

Email address
m.faryadras@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
2020-12-21, 1399/10/01

Actual recruitment end date
2021-01-19, 1399/10/30

Trial completion date
2021-01-19, 1399/10/30

Scientific title
A randomized trial comparing surfactant administration using InSurE technique and the minimally invasive

surfactant therapy in preterm infants at the age of 28 to 36 weeks of gestation and respiratory distress syndrome

Public title
Treatment of respiratory distress syndrome in preterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age of 28-37 weeks With distress syndrome Requiring Fraction of inspired oxygen>40 Treatment with surfactant in less than 24 hours after birth
Exclusion criteria:
Suffering of congenital heart abnormalities APGAR score<5 Suffering from any congenital disease
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator

Sample size
Target sample size: **112**
Actual sample size reached: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to the intervention and control groups using block randomization. The patients will be randomly assigned to the intervention and control groups using block randomization. Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number (between 1 and 6) to each of them 3)Choosing random numbers between 1 and 6 4) Defining the treatment assignment list.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person evaluating the outcome will be unaware of the type of intervention
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-09-14, 1398/06/23
Ethics committee reference number
IR.UMSHA.REC.1398.457

Health conditions studied

1

Description of health condition studied
Neonatal respiratory distress syndrome
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
respiratory support
Timepoint
First week of birth
Method of measurement
Investigation of FIO2 and analysis of arterial blood gases

2

Description
Hospitalization duration
Timepoint
During hospitalization
Method of measurement
Review of infant medical records

3

Description
Mortality
Timepoint
During hospitalization
Method of measurement
Review of infant medical records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Participants take 200 mg/kg surfactant (Curosurf Chiesi Farmaceutici, Parma, Italy)by MIST method. Neonatal intubation and who are receiving2000 mg/kg surfactants in 1-3 minutes via feeding tube.
Category
Treatment - Devices

2

Description
Intervention group: Participants take 200 mg/kg surfactant (Curosurf Chiesi Farmaceutici, Parma, Italy) by INSUR method.They receive 200 mg/kg surfactant in 1-3 minutes from a feeding tube via a thin intratracheal catheter (Insure method) during spontaneous breathing.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiyeh Hospital
Full name of responsible person
Dr Mohammad Kazem Sabzehei
Street address
Fatemiyeh Hospital, Kermanshah street, Hamedan
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
Mk_sabzehei@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
vc_research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mohamad Kazem Sabzehei
Position
Hamadn
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Fatemiyeh Hospital, Kermanshah street, Hamedan
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
Mk_sabzehei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohamad Kazem Sabzehei
Position
Neonatologist-assistant professor

Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Fatemiyeh Hospital, Kermanshah street, Hamedan
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0717
Email
Mk_sabzehei@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohamad Kazem Sabzehei
Position
Neonatologist- assistant professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Fatemiyeh Hospital, Kermanshah street, Hamedan
City
Hamadan
Province
Hamadan
Postal code
+98 81 3838 0717
Phone
+98 917 332 4977
Email
Mk_sabzehei@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information"
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available