

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 Fatemeh 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	Research Ethic Committee of Hamadan University of Medical Sciences
Public title Treatment of respiratory distress syndrome in preterm infants	Street address Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
Purpose Treatment	City Hamadan
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	Province Hamadan
Age From 1 day old to 28 days old	Postal code 6517838695
Gender Both	Approval date 2019-09-14, 1398/06/23
Phase 2-3	Ethics committee reference number IR.UMSHA.REC.1398.457
Groups that have been masked Investigator	Health conditions studied
Sample size Target sample size: 112 Actual sample size reached: 112	1
Randomization (investigator's opinion) Randomized	Description of health condition studied Neonatal respiratory distress syndrome
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.	ICD-10 code P22.0
Blinding (investigator's opinion) Single blinded	ICD-10 code description Respiratory distress syndrome of newborn
Blinding description The person evaluating the outcome will be unaware of the type of intervention	Primary outcomes
Placebo Not used	1
Assignment Parallel	Description respiratory support
Other design features	Timepoint First week of birth
Secondary Ids empty	Method of measurement Investigation of FIO2 and analysis of arterial blood gases
Ethics committees	2
1	Description Hospitalization duration
Ethics committee Name of ethics committee	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 receiving 2000 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

Fatemiye Hospital

Full name of responsible person

Dr Mohammad Kazem Sabzehei

Street address

Fatemiye Hospital, Kermanshah street, Hamedan

City

Hamedan

Province

Hamedan

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,
Hamedan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamedan

Province

Hamedan

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

Hamedan

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Fatemiye Hospital, Kermanshah street, Hamedan

City

Hamedan

Province

Hamedan

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

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

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

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