

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing of short term outcome of treatment with two porcine and bovine natural surfactant in neonatal respiratory distress, a randomized clinical trial study

Protocol summary

Summary

The aim of present study was to compare of short term outcome of treatment with two porcine and bovine surfactant in neonatal respiratory distress. In a double blind single center clinical trial study, 100 premature neonates who referred to Alzahra Hospital of Tabriz University of Medical Sciences and needs surfactant treatment will select randomly and with using random numbers table will allocate in two groups of intervention and control group. Inclusion criteria are, premature neonates, birth weight less than or equal 1250 grams, respiratory distress, and indication for surfactant. Exclusion criteria are congenital heart disease, and fifth minute Apgar score less than five. In intervention group neonates will receive 2.5 cc per kg porcine surfactant endotracheal within two hours of birth and in control group neonates receive 5 cc per kg bovine surfactant endotracheal within two hours of birth. Patients will follow up for 2 weeks. Lipid profile level will measure at beginning of study, first month, third month, and also at the end of 6th month. Improvement of neonatal respiratory distress is as primary variable of study and side effect is as secondary variable of present study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092119250N1**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Majid Mahallei

Name of organization / entity

Department of Pediatrics, Tabriz University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 1949

Email address

m.mahallei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of short term outcome of treatment with two porcine and bovine natural surfactant in neonatal respiratory distress, a randomized clinical trial study

Public title

Comparing of short term outcome of treatment with two porcine and bovine surfactant in neonatal respiratory distress

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: premature neonates; birth weight less than or equal 1250 grams; respiratory distress; indication for surfactant. Exclusion criteria: congenital heart disease; fifth minute Apgar score less than five.

Age
To **1 day** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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

Tabriz University of Medical Sciences.

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Eastern Azerbaijan, Iran.

City

Tabriz

Postal code

Approval date

2016-03-07, 1394/12/17

Ethics committee reference number

TBZMED.REC.1394.1198

Health conditions studied

1

Description of health condition studied

Respiratory distress

ICD-10 code

P22.8

ICD-10 code description

Other respiratory distress of newborn

Primary outcomes

1

Description

Improvement of Respiratory distress

Timepoint

During admission

Method of measurement

Physical examination

Secondary outcomes

1

Description

Adverse effects

Timepoint

2 weeks later

Method of measurement

Patient follow up

Intervention groups

1

Description

In intervention group: neonates will receive 2.5 cc per kg porcine surfactant endotracheal within two hours of birth.

Category

Treatment - Drugs

2

Description

In control group: neonates will receive 5 cc per kg bovine surfactant endotracheal within two hours of birth.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Dr Majid Mahallei

Street address

Alzahra Hospital of Tabriz University of Medical Sciences, Artesh Street, Tabriz, Eastern Azerbaijan, Iran.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

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, Tabriz University of Medical Sciences.

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

Tabriz University of Medical Sciences.

Full name of responsible person

Dr Majid Mahallei

Position

Subspecialty of Neonates.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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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