

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Efficacy of three Natural Surfactants, Curosurf ,Survanta and Alveofact, in Treatment of Respiratory Distress Syndrome in Infants

Protocol summary

Summary

Introduction: Use of natural surfactant rather than synthetic surfactants are preferred in the treatment of neonatal respiratory distress syndrome, although several different types of natural surfactant in Iran (Alveofact, curosurf and Survanta) is available but the preferred type and the magnitude of effect of Surfactants is largely unknown . The purpose of this randomized clinical trial is comparing the effects of surfactants on gas exchange and clinical outcomes in infants with respiratory distress syndrome. for evaluating this aim, 165 Infants born in Talegani Hospital in Tabriz at a gestational age of 36 weeks or less with respiratory distress syndrome in a prospective, randomized clinical trial were studied. inclusion criteria was all under 38 weeks GA neonate without anomaly and Exclusion criteria were congenital anomalies, birth asphyxia (Apgar score less than 4 at 5 minutes) and gestational age over 36 weeks. Infants were randomly assigned by computer randomization to three groups: the first group received Alveofact, Group II received Curosurf and Group III proctant alfa (Survanta) with INSUR method .clinical standards (the oxygen demand, the incidence of ventilator dependency, BPD, IVH and ..) and blood gases were analyzed and recorded in three group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411028680N5**

Registration date: **2014-11-21, 1393/08/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-21, 1393/08/30

Registrant information

Name

Mirhadi Mussavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2014-10-19, 1393/07/27

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of three Natural Surfactants, Curosurf ,Survanta and Alveofact, in Treatment of Respiratory Distress Syndrome in Infants

Public title

Evaluating the Efficacy of Surfactants, Curosurf ,Survanta and Alveofact, in Respiratory Distress Syndrome in Infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infants born at a gestational age of 36

weeks or less Exclusion criteria: congenital anomalies, birth asphyxia (Apgar score less than 4 at 5 minutes) and gestational age over 36 weeks

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: **165**

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

Ethics commitee ofTabriz University Of Medical Sciences

Street address

Golgasht Av

City

Tabriz

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

8745

Health conditions studied

1

Description of health condition studied

Neonatal respiratory distress

ICD-10 code

P22

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Base exchess change

Timepoint

After intervention

Method of measurement

Blood gas analysis

2

Description

Pco2 Change

Timepoint

After intervention

Method of measurement

Blood gas analysis

3

Description

duration of oxygen dependency

Timepoint

Up to 7 days after intervention

Method of measurement

Oxygen Saturation analysis with pulseoxymetry

4

Description

CPAP Failure

Timepoint

After intrvention

Method of measurement

Blood gas analysis

Secondary outcomes

1

Description

Intraventricular hemorrhage

Timepoint

Up to 7 days after intervention

Method of measurement

Brain sonography

2

Description

Patent ductus arteriosus

Timepoint

Up to 7 days after intervention

Method of measurement

Echocardiography

3

Description

Broncho pulmonary dysplasia

Timepoint

up to 28 days old

Method of measurement

Chest X-ray

4

Description

Mortality

Timepoint

Up to 28 days after intervention

Method of measurement

clinical finding

Intervention groups

1

Description

1 st dose of Survanta 100 mg/kg via endotracheal tube

Category

Treatment - Drugs

2

Description

1 st dose of Curosurf 200 mg/kg via endotracheal tube

Category

Treatment - Drugs

3

Description

1 st dose of Alveofact 100 mg/kg via endotracheal tube

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Mussavi,Mirhadi

Street address

Artesht Av

City

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Rashidi Mohammadreza

Street address

Golgasht av

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 of 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

Mussavi,Mirhadi

Position

Neonatologist /Assistant professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mussavi,Mirhadi

Position

Neonatologist

Other areas of specialty/work

Street address

Alzahra Hospital

City

Tabriz

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Email

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Web page address

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