Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparing the efficacy of two surfactant (alveofact, crusorf) in complications and duration of mechanical ventilation for management of respiratory distress syndrome in preterm infants

Protocol summary

Summary

Objectives: to compare the efficacy of two different surfactant in the treatment of respiratory distress syndrome. Design: randomized controlled clinical trial. Setting and conduct: Preterm neonates that admitted in NICU of AL Zahra or Children hospital with respiratory distress syndrome who need surfactant replacement therapy will enrolled in this study . Participants: Eighty pre term infants with gestation age less than 32 weeks and birth weight less than 1500 gram randomly allocated in two groups. Forty preterm neonates will receive alveofact 1.2 ml/kg and 40 neonates receive crusorf 2.5 ml/kg intratrachealy.Infants with major congenital anomalies and and severe birth asphyxia will exclude from study. Main outcome is the need for assisted ventilation for 7 days. Secondary outcomes are mortality before discharge due to prematurity, complications of RDS including pulmonary hemorrhage, bronchopulmonary dysplasia, PDA, air leak syndromes, retinopathy of prematurity, intra ventricular hemorrhage and sepsis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212123915N8**
Registration date: **2013-01-09, 1391/10/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-09, 1391/10/20

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2012-09-30, 1391/07/09

Expected recruitment end date

2013-10-01, 1392/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the efficacy of two surfactant (alveofact, crusorf) in complications and duration of mechanical ventilation for management of respiratory distress syndrome in preterm infants

Public title

comparing two surfactant in management of respiratory distress syndrome in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: gestation age less than 32 weeks; birth

weight less than 1500 gr exclusion criteria:congenital malformations; severe birth asphyxia

Age
To **1 year** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tabriz university of Medical Sciences

Street address
Tabriz university of medical sciences, Golgasht street, Tabriz

City
Tabriz

Postal code

Approval date
2012-10-15, 1391/07/24

Ethics committee reference number
91137

Health conditions studied

1

Description of health condition studied
respiratory distress syndrome

ICD-10 code
p22

ICD-10 code description
respiratory distress syndrome

Primary outcomes

1

Description
mechanical ventilation

Timepoint
daily for 7 days

Method of measurement
need for intubation and mechanical ventilation

Secondary outcomes

1

Description
mortality

Timepoint
daily tilldischarge

Method of measurement
death

2

Description
complications

Timepoint
till discharge

Method of measurement
presence of pulmonary hemorrhage, bronchopulmonary dysplasia, air leak syndrome, retinopathy of prematurity, sepsis

Intervention groups

1

Description
intratracheal alveofact 1.2 ml/ kg after diagnosis of RDS and repeat if needed every 12 hours till 3 doses

Category
Treatment - Drugs

2

Description
intratracheal crusorf 2.5 ml/kg at first dose and 1.25 ml/kg if repeated dose needed every 12 hours till 3 doses

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al Zahra Hospital

Full name of responsible person
Manizheh Mostafa Gharehbaghi

Street address
South Artesh street, Al Zahra hospital

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Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice Chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Dr Rashidi
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Golgasht street, Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research vice Chancellor 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
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Person responsible for updating data

Contact

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