

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of prophylactic surfactant in first 6 hour of life on outcome of premature neonate less than 1500 gram

Protocol summary

Summary

The purpose of this study is comparing the side effects of respiratory distress syndrome between premature neonates having birth weight of less than 1500 gram taking prophylactic surfactant in the first 6 hours after birth and those who do not take the surfactant. Also we want to compare the decrease rate of side effects in the routine prophylactic method (BW<1250 gram in the first 2 hours of birth) and the recommended one (BW<1500 gram in the first 6 hours of birth) to reach the appropriate time and weight for prophylactic treatment. Our study is a non-blinded randomized clinical trial which its entrance criteria is a neonate suffering from respiratory distress syndrome (hyaline membrane disease) with body weight of less than 1500 gram and its exit criteria are body weight of more than 1500 gram or intrauterine growth retardation. This research has been performed on 182 neonates <1500 gram during 1 year, that 90 cases were in the intervention group (taking surfactant) and 92 ones were in the control group (not taking any surfactant). In this study, the surfactant solution was survanta, ordered through the dose of 2 ml/kg as soon as possible (before passing the first 6 hours of birth) via tracheal tube, as many as it was required. At the end the, main outcome (death) and the other outcomes including pulmonary hemorrhage, pneumothorax, intracranial hemorrhage and PDA were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905104486N1**

Registration date: **2010-09-25, 1389/07/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-25, 1389/07/03

Registrant information

Name

Jabarali Safaei

Name of organization / entity

Kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

00988314276310, 00988314276311(2245)

Email address

dr.jsafaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic surfactant in first 6 hour of life on outcome of premature neonate less than 1500 gram

Public title

Effect of prophylactic surfactant on outcome of premature neonate

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION CRITERIA: gestational age < 34 weeks, birth weight <1500 gram , respiratory distress syndrome (hyaline membrane disease). EXCLUSION CRITERIA: gestational age > 34 weeks, birth weight >1500 gram, intrauterine growth retardation, other respiratory disease without RDS.

Age

To **21 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **182**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

Street address

No. 2, Sepah square

City

Kermanshah

Postal code**Approval date**

2010-05-17, 1389/02/27

Ethics committee reference number

420/9234 /7/پ

Health conditions studied**1****Description of health condition studied**

Respiratory distress syndrom of newborn

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes**1****Description**

death

Timepoint

during the study

Method of measurement

physical exam

Secondary outcomes**1****Description**

pulmonary hemorrhage

Timepoint

while studying

Method of measurement

physical exam & chest-x-ray

2**Description**

pneumothorax

Timepoint

while studying

Method of measurement

physical exam & chest-x-ray

3**Description**

intraventricular hemorrhage (IVH)

Timepoint

while studying

Method of measurement

physical exam & cranial sonography

4**Description**

patent ductus arteriosus (PDA)

Timepoint

while studying

Method of measurement

physical exam & echocardiography

Intervention groups**1****Description**

Surfactant solution (survanta), 2 ml per KG of body weight, as soon as possible (before passing the first 6 hr of birth), via tracheal tube, as many as it was required

Category

Treatment - Drugs

2

Description

no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Jabarali Safaei

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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No. 2, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Aliasghar Alipour

Position

Neonatologist, assistant professor

Other areas of specialty/work

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Newborn ward, Pediatric group, EmamReza hospital

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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