

# 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

##### Street address

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

#### Street address

Newborn ward, Pediatric group, EmamReza hospital

#### City

Kermanshah

#### Postal code

#### Phone

00988314276310 - 00988314276311 ( 2292 )

#### Fax

#### Email

a-a\_alipour\_md@kums.ac.ir ,

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#### Web page address

## Person responsible for scientific 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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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Jabarali Safaei

##### Position

MD, resident

##### Other areas of specialty/work

##### Street address

Pediatric group, Emam Reza hospital

##### City

Kermanshah

##### Postal code

6714415333

##### Phone

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dr.jsafaei@kums.ac.ir , tanhaj14@gmail.com

##### 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*