Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Evaluation of effect of vitamin E in prevention of intraventricular hemorrhage in preterm neonates with gestational age below 30 weeks in alzahra hospital

Protocol summary

Summary

This randomized clinical trial was conducted to evaluate effect of vitamin E in prevention of intraventricular hemorrhage in preterm newborn with gestational age less than 30 week born in Alzahra Hospital affiliated to Isfahan University of Medical Sciences since fall 2014 to spring 2016. written informed consent was taken from the child's parents. The infants were randomly allocated to either the case or the control group by a simple randomization method using a table of random numbers. The inclusion criteria were prematurity with gestational age equal or less than 30 weeks, no need for mechanical ventilation, normal blood pressure, 5-minute Apgar scores of ≥7, no presence of sepsis, abdominal distension, bile secretion and IVH. The neonates who needed sodium bicarbonate or resuscitation or mechanical ventilation in the first three days after birth were excluded from study. Besides that, abdominal distension and bile secretion during the study were considered other exclusion criteria. Seventy six neonates with 30-week gestational age or less were enrolled in this study. The neonates were randomly divided in two groups matched for age and gender. Immediately after birth, all neonates underwent brain sonography to determine if they had IVH. For the cases group (consist of 38 newborn) 10 units of vitamin E (1 cc of vitamin E per a drop) and in the control group (consist of 38 newborn) 1 cc distilled water was administered orally through orogastric tube for three days. In the fourth and seventh days after birth, brain sonography was conducted to evaluate IVH in the neonates. The presence of sepsis, incidence of necrotizing enterocolitis (NEC) and hypotension, drug reaction and mortality was recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042521910N2**
Registration date: **2017-01-26, 1395/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-26, 1395/11/07

Registrant information

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Behzad Barekatain
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2014-09-21, 1393/06/30

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of effect of vitamin E in prevention of intraventricular hemorrhage in preterm neonates with gestational age below 30 weeks in alzahra hospital

Public title
effect of vitamin E in intraventricular hemorrhage in preterm neonates

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: preterm infants with gestational age less than 30weeks; lack of congenital malformations or CNS disease at birth; the infant's mother take one course of steroid prior to delivery; absent of maternal chorioamnionitis; lack of use of mechanical ventilation; oxygen saturation greater than 90%; normal blood pressure; APGAR score greater than 7 at 5 minute; lack or sepsis; lack of IVH at the beginning of study; lack of abdominal distention at the beginning of study. Exclusion criteria: need for administration of sodium bicarbonate during first 3 days of birth; need of resuscitation during first 3 days of birth; abdominal distention during vit E administration; need for mechanical ventilation.

Age
To **1 month** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciense

Street address
Hezarjerib boulevard, Isfahan University of Medical Sciense

City
Isfahan

Postal code

Approval date
2015-10-31, 1394/08/09

Ethics committee reference number
IR.MUI.REC.1394.3.569

Health conditions studied

1

Description of health condition studied
Intraventricular hemorrahge

ICD-10 code
P52.9

ICD-10 code description
Intracranial (nontraumatic) haemorrhage of fetus and newborn, unspecified

Primary outcomes

1

Description
Intra Ventricular Hemorrahge

Timepoint
4th and 7th days

Method of measurement
Brain Sonography

Secondary outcomes

1

Description
Sepsis

Timepoint
During Study

Method of measurement
Clinical Sign and Blood Culture

2

Description
Necrotizing Enterocolitis

Timepoint
During Study

Method of measurement
Clinical Sign and Abdominal Graphy

3

Description
Death

Timepoint
During Study

Method of measurement
Observation

Intervention groups

1

Description
In Intervention group we prescribed 10 unit of Vit E (equall to 1 cc) orally via orogastric tube once in day for 3 days
Category
Prevention

2

Description
In control group we prescribed 1 cc of distilled water orally via orogastric tube once in day for 3 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Behzad Barekatain
Street address
Isfahan, Sofeh street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Isfahan University of Medical Sciense
Full name of responsible person
Mehdi Nematbakhsh
Street address
Hezarjerib boulevard, Isfahan University of Medical Sciense
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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 Isfahan University of Medical Sciense
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
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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