

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Name

Behzad Barekatin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6670

Email address

b_barekatin@med.mui.ac.ir

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 Science

Street address

Hezarjerib boulevard, Isfahan University of Medical Science

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 hemorrhage

ICD-10 code

P52.9

ICD-10 code description

Intracranial (nontraumatic) haemorrhage of fetus and newborn, unspecified

Primary outcomes

1

Description

Intra Ventricular Hemorrhage

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 (equal 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 Barekatin

Street address

Isfahan, Sofeh street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Science

Full name of responsible person

Mehdi Nematbakhsh

Street address

Hezarjerib boulevard, Isfahan University of Medical Science

City

Isfahan

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 Science

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

Isfahan University of Medical Sciences

Full name of responsible person

Samira Saraeian

Position

Resident of Pediatrics

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Behzad Barekatin

Position

Academic member of Isfahan University of Medical Sciences, Neonatologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Behzad Barekatin

Position

Academic member of Isfahan University of Medical Sciences, Neonatologist

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

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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