

# 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  $\geq 7$ , 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

#### Street address

Pediatric office, Imam hosein hospital, Imam khomeini street, Isfahan

#### City

Isfahan

#### Postal code

#### Phone

+98 31 3386 8247

#### Fax

#### Email

dr.samira.saraeian@gmail.com

#### Web page address

## 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

#### Street address

Nom 302, Arian apartment building, Mehran ave, Moshtagh st, Isfahan

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Isfahan

#### Postal code

#### Phone

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b\_barekatin@med.mui.ac.ir

#### Web page address

## 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**

Nom 302, Arian apartment building, Mehran ave,  
Moshtagh st, Isfahan

**City**

Isfahan

**Postal code****Phone**

+98 31 3261 6670

**Fax****Email**

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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*