

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Protocol summary

Study aim

Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Design

This randomized clinical trial was conducted to evaluate effect of vitamin E in prevention of hyper bilirubinemia in preterm newborn with gestational age between 34 to 37 weeks born in Alzahra and Shahidbeheshti Hospital affiliated to Isfahan University of Medical Sciences. 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. One hundred neonates with gestational age between 34 to 37 weeks were enrolled in this study. The neonates were randomly divided in two groups matched for age and gender. Immediately after birth For the cases group (consist of 50 newborn) 10 units of vitamin E (1 cc of vitamin E per a drop) and in the control group (consist of 50 newborn) 1 cc distilled water was administered orally for five days. In the 0,24,48,72 and 96 Hour of life, Transcutaneous Billirubinometry was conducted to evaluate level of bilirubin in neonates of two groups. The results was analyzed via t-test and x2-test. P value less than 0/05 was considered significant.

Settings and conduct

Alzahra and Shahid beheshti Hospitals in Isfahan

Participants/Inclusion and exclusion criteria

Preterm newborns with GA between 34 to 37 weeks
Exclusive breast feeding
Apgar score > 7 in fifth minute
lack of neonatal sepsis
lack of abdominal distentions or lavage
lack of history of exchange transfusion in previous sibling

Intervention groups

For the cases group (consist of 50 newborn) 10 units of vitamin E (1 cc of vitamin E per a drop) and in the control group (consist of 50 newborn) 1 cc distilled water was prescribed orally for five days

Main outcome variables

Neonatal Jaundice

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150423021910N4**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-04, 1397/10/14**

Update count: **0**

Registration date

2019-01-04, 1397/10/14

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

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Public title
Effect of Vit E on billirubin level in preterm newborns

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
preterm newborns with GA between 34 to 37 weeks
Exclusive breast feeding Apgar score > 7 at fifth minute of life
Exclusion criteria:
lack of abdominal distention or lavage lack of history of exchange transfusion in previous siblings lack of neonatal sepsis

Age
From **1 day** old to **1 month** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **5**
Measurement of billirubin via Transcutaneous Billirubinometer

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random number was used. We use 100 tumultuous numerical table and we selected columns in the form of decussate and assigned its numbers to each groups (intervention and control groups)

Blinding (investigator's opinion)
Double blinded

Blinding description
In our study the student and neonatal unit staffs dont know which types of drugs (Vit E or placebo) is prescribed. Transcutaneous Billirubinometry was performed by student that did not know which type of drugs prescribed by physician.

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 Sciences

Street address

Hezarjerib boulevard, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-05-07, 1396/02/17

Ethics committee reference number

IR.MUI.REC.1396.3.071

Health conditions studied

1

Description of health condition studied

Neonatal Jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Neonatal Jaundice

Timepoint

In 0 , 24 , 48 , 72 , 96 Hours

Method of measurement

Transcutaneous Billirubinometer

Secondary outcomes

1

Description

Sepsis

Timepoint

During Study

Method of measurement

Clinical Sign and Blood Culture

Intervention groups

1

Description

Intervention group: In Intervention group we prescribed

10 unit of Vit E (equal to 1 cc) orally once in day for 5 days

Category

Prevention

2

Description

Control group: In control group we prescribed 1 cc of distilled water orally once in day for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Behzad Barekatin

Street address

Sofeh street, Isfahan

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2

Recruitment center

Name of recruitment center

Shahidbeheshti Hospital

Full name of responsible person

Behzad Barekatin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooi Javanmard

Street address

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nahid Moradi

Position

Student of medicine

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Behzad Barekatin

Position

Faculty member of Isfahan University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Position

Faculty member of Isfahan University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No Additional Informations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

No Additional Informations

When the data will become available and for how long

No Additional Informations

To whom data/document is available

No Additional Informations

Under which criteria data/document could be used

No Additional Informations

From where data/document is obtainable

No Additional Informations

What processes are involved for a request to access data/document

No Additional Informations

Comments