Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Effect of vitamin E Supplementation on the Treatment of Neonates with Hyperbilirubinemia: A Double-blind Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of vitamin E supplementation on the treatment of newborns with hyperbilirubinemia

Design
This controlled, parallel-group, double-blind, randomized, phase 3 clinical trial is conducted on 70 infants. Randomization of infants into drug and placebo groups was done using the Random between function of Excel software.

Settings and conduct
The study is conducted in the Neonatal Department of Besat Hospital located in Sanandaj, Kurdistan, Iran. In this study, 70 babies are randomly placed in two groups receiving vitamin E and dextrose. Nurses and parents of infants are blinded to the type of drug received. In order to perform blinding, the drugs are kept in dark and same-colored bottles labeled A and B and given to babies using a dropper.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Term newborns with hyperbilirubinemia admitted to the neonatal department of Besat Hospital of Sanandaj in 2022, gestational age from 37 weeks to 42 weeks and 6 days, birth weight from 2500 gr to 4000 gr Exclusion criteria: Evidence of infection, congenital malformation, history of phenobarbital use, hypothyroidism, intrauterine growth restriction, oral intolerance, mechanical ventilation

Intervention groups
The group receiving vitamin E oral drops at the rate of 0.5 cc once a day. Placebo group: the group receiving 10% dextrose serum in the amount of 0.5 cc once a day

Main outcome variables
Average serum total bilirubin Average serum indirect bilirubin The amount of changes in the mean total serum bilirubin before and after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220806055625N2**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date
2022-12-26, 1401/10/05

Registrant information

Name
Siros Hemmatpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3362 7751

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-01, 1401/09/10

Expected recruitment end date
2023-01-30, 1401/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effect of vitamin E Supplementation on the Treatment of Neonates with Hyperbilirubinemia: A Double-blind Randomized Clinical Trial

Public title
Investigating the effect of vitamin E on the Treatment of Neonatal Hyperbilirubinemia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Term infants with hyperbilirubinemia admitted to the neonatal department of Besat Sanandaj Hospital in 1401 Gestational age from 37 weeks to 42 weeks and 6 days Birth weight from 2500 Grams to 4000 Grams

Exclusion criteria:
Evidence of infection Congenital malformation History of phenobarbital use in mother Hypothyroidism Inappropriate intrauterine growth Oral intolerance Mechanical ventilation

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Neonates will be completely randomly assigned to two groups receiving vitamin E and placebo (10% Dextrose serum). To perform randomization, Excel software is used with the Random between command. To carry out this process, a two-digit code is assigned to each of the people entered into the study, and then using the software, these numbers are randomly selected to enter each of the groups. Odd or even numbers will be assigned to one group each.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the design is double-blind; so that the neonates studied in two groups and their families and clinical caregivers are blinded to the intervention and intervention status.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Kurdistan University of Medical Sciences, Pasdaran Street

City
Sanandaj

Province
Kurdistan

Postal code
661776796

Approval date
2022-03-12, 1400/12/21

Ethics committee reference number
IR.MUK.REC.1400.326

Health conditions studied

1

Description of health condition studied
Neonatal Hyperbilirubinemia

ICD-10 code
P58

ICD-10 code description
Neonatal jaundice due to other excessive hemolysis

Primary outcomes

1

Description
Mean serum total bilirubin

Timepoint
Serum total bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement
Taking blood samples from the infants in the study at 24 hours, 48 hours and 72 hours after the intervention by a trained nurse and sending them to the lab

2

Description
Mean serum indirect bilirubin

Timepoint
Serum indirect bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement
Taking blood samples from the infants in the study at 24 hours, 48 hours and 72 hours after the intervention by a trained nurse and sending them to the lab

3

Description

The amount of changes in the mean serum total bilirubin

Timepoint

Before the intervention and 24, 48 and 72 hours after the intervention

Method of measurement

Comparing the average total serum bilirubin before the intervention and the average total serum bilirubin obtained 24, 48 and 72 hours after the intervention.

Secondary outcomes

1

Description

The average number of hospitalization days of newborns in two groups

Timepoint

Number of hospitalization days 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement

Registration the number of hospitalization days of the newborns according to the file by a trained nurse

2

Description

The average hours of receiving phototherapy for newborns in two groups

Timepoint

Number of hours receiving phototherapy 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement

Registering data of number of hours receiving phototherapy by a trained nurse

3

Description

Possible complications of vitamin E drug

Timepoint

24 hours, 48 hours and 72 hours after the intervention in two groups

Method of measurement

A booklet containing the desired questions related to possible complications (these complications are selected by reviewing the literature) is provided to the mothers of babies and is followed up by a trained nurse.

Intervention groups

1

Description

Intervention group: 35 infants are placed in the group receiving vitamin E orally with a dose of 0/5 cc (equivalent to 10 drops) orally once a day, on the first, second and third days of the intervention.

Category

Treatment - Drugs

2

Description

Control group: 35 infants are placed in the group receiving 10% dextrose serum orally on the first, second and third days of the intervention. Dextrose serum in the amount of 0/5 cc orally once a day is administered to infants in the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Sirus Hematpour

Street address

Keshavarz Street

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6618634683

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Info@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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Abidar street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

1

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
Sanandaj University of Medical Sciences

Full name of responsible person
Sirous Hematpour

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Sirous Hematpour

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available