Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Zinc on Hyperbilirubinemia of healthy and normal newborns, a clinical trial

Protocol summary

Study aim
Evaluate the effect of Zinc on Hyperbilirubinemia in newborn babies in Zanjan

Design
Clinical trial with control group, parallel group, double blinded, randomized

Settings and conduct
In this double-blind, randomized clinical trial, 112 healthy newborns with physiologic jaundice were equally divided into two groups receiving zinc and placebo. Each day, 10 mg of zinc (5 cc of syrup) was administered to the case group and also 5 cc of placebo was administered to the control group and the total bilirubin levels of the second, third, fourth and fifth day and duration of hospitalization and phototherapy were compared. Blinded people: Participant- Care provider

Participants/Inclusion and exclusion criteria
Participants:Healthy children with jaundice admitted to the neonatal ward Inclusion criteria: term infants; breast-feeding; jaundice; photo-therapy; serum bilirubin 15-20 mg / dL; age of 3 to 7 days; using no other drug
Exclusion criteria: recent weight loss; infection; hemolytic disease; oral intolerance; congenital birth defects; gastrointestinal anomalies; parental dissatisfaction for participation in the study; need for ventilators; need for blood transfusion

Intervention groups
Intervention group: Patients in the intervention group will receive 5 mg zinc (2.5 ml) of 10 mg per 5 ml Zinc Sulfate syrup produced by Donya-ye-Behdasht company twice a day from admission day until discharging from hospital.
Control group: Patients in the control group will receive 2.5 ml of placebo syrup twice a day from admission day until discharging from hospital, which producted in the Faculty of Pharmacy, Zanjan University of Medical Sciences, completely similar to the main drug.

Main outcome variables
Serum total bilirubin in hospitalization days and hospitalization days

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017061515835N5**
Registration date: **2017-10-14, 1396/07/22**
Registration timing: **prospective**

Last update: **2018-12-13, 1397/09/22**
Update count: **2**

Registration date
2017-10-14, 1396/07/22

Registrant information

Name
Parisa Khoshnevisasl

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Zanjan University of Medical Sciences, vice chancellor for research

Expected recruitment start date
2017-11-01, 1396/08/10

Expected recruitment end date
2018-09-01, 1397/06/10

Actual recruitment start date
2017-12-22, 1396/10/01

Actual recruitment end date
2018-08-23, 1397/06/01

Trial completion date
2018-08-23, 1397/06/01

Scientific title
The effect of Zinc on Hyperbilirubinemia of healthy and normal newborns, a clinical trial

Public title
The effect of Zinc on Hyperbilirubinemia of newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Term infants Breast-feeding Jaundice Photo-therapy Serum bilirubin 15-20 mg/dL Age 3 to 7 days Using no other drug
Exclusion criteria:
Recent weight loss Infection Hemolytic disease Oral intolerance Congenital birth defects Gastrointestinal anomalies Parental dissatisfaction for participation in the study Need for ventilators Need for blood transfusion
Age
From **3 days** old to **7 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **112**
Actual sample size reached: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization is done. Patients are randomly assigned to one of the two intervention and placebo groups. The randomization unit is individual. Random number table is used. The random number table contains numbers from 1 to 112 in and we will read these numbers from up to down and we will write the succession. Then we will give Zinc sulfate to numbers 1 to 56 and Placebo to numbers 57 to 112. Then for hiding the sequence we will use sealed, opaque envelopes. Every one who will enter our study will choose one envelope which has one number of the random number table in it and his group will be defined.
Blinding (investigator's opinion)
Double blinded
Blinding description
drug packs are marked by the main investigator with two signs A or B. Medication packs are delivered to the care provider with signs A or B. The care provider and the participant are unaware of the contents of the A or B envelopes. After the end of the study, specific intervention of each patient would be explained to him. A contains zinc sulfate and B contains placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commite of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi square, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2017-06-06, 1396/03/16
Ethics committee reference number
ZUMS.REC.1396.30

Health conditions studied

1

Description of health condition studied
Neonatal physiological jaundice
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Serum total bilirubin in hospitalization days
Timepoint
One time measuring before prescribing of Zink and immediately after that daily measurment in three days
Method of measurement
Colorimetric method by Lathe and Ruthven

2

Description
Hospitalization days
Timepoint
Patient's discharging day
Method of measurement
Computation the number of hospitalization days from admission to discharge

Secondary outcomes

empty

Intervention groups

1

Description
Daily administration of 5 mg (2.5 ml) twice daily of 10 mg per 5 ml Zinc Sulfate syrup produced by Donya-ye-Behdasht company in case group until the newborn is admitted
Category
Treatment - Drugs

2

Description
Daily administration of 2.5 ml twice daily placebo produced by Faculty of Pharmacy, Zanjan University of Medical Sciences in control group until the newborn is admitted
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Dr. Parisa Khoshnevis Asl
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Ayatollah Mousavi Hospital, Gavazang street, Zanjan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Parisa Khoshnevis Asl
Position
Pediatrician, Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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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