

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 produced 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 1427 2737

##### Email address

khoshnevis@zums.ac.ir

##### 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 committee 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 Zinc and immediately after that daily measurement 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, Zanzan 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

##### Street address

Ayatollah Mousavi Hospital, Gavazang street, Zanzan, Iran

##### City

Zanzan

##### Province

Zanzan

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4515613191

##### Phone

+98 24 3315 6319

##### Email

international@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanzan University of Medical Sciences

##### Full name of responsible person

Dr. Alireza Shoghli

##### Street address

Zanzan University of Medical Sciences, Azadi square, Zanzan, Iran

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Zanzan

##### Province

Zanzan

##### Postal code

4515613191

##### Phone

+98 24 3315 6319

##### Email

international@zums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Zanzan 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

Zanzan 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

##### Street address

Pediatrics department, Ayatollah Moussavi Hospital, Gavazang street, Zanzan, Iran

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

khoshnevis@zums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zanzan 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**

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**Web page address**

## 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

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zanzan 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

**Street address**

Pediatrics department, Ayatollah Moussavi Hospital,