Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral zinc administered on the bilirubin serum level in the icterus mature newborns

Protocol summary

Summary

Purpose: Evaluation of the effect oral zinc on the serum bilirubin levels in term neonates. All the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH) with serum bilirubin level more than 15mg/dl have been considered as the case group and received phototherapy according to the ACH phototherapy protocol. On the other hand newborns with serum bilirubin level more than 15mg/dl have been considered as control group. In both groups phototherapy were done according to the ACH phototherapy protocol. Bilirubin was cheeked by spectrophotometry method by chemical kits and serum zinc level was checked by auto analyzer; in two times before the photo therapy start and at the discharge time. By choosing 30 cases in the each group it would be possible to detect the effect of one unit differences between the case and control group, with 95 percent confidence interval and 80 percent ability test. The study is double blinded; study phases are trial 1 and 2 done in one center (Amirkola Children's Hospital). Performed via a random number table. Inclusion criteria: Full term newborns, with of age for more than 72 hours and serum bilirubin level more than 15mg/dl. Exclusion criteria: All babies who received medication such as zinc sulphate and phenobarbital by mothers or newborn. Intervention: Oral zinc administration. The primary consequences: Determination of serum bilirubin level. The secondary consequence: detecting serum zinc levels that would be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072629077N1**
Registration date: **2017-03-16, 1395/12/26**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

bahram ranjbar

Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral zinc administered on the bilirubin serum level in the icterus mature newborns

Public title

The effect of oral zinc administered on the bilirubin serum level in the icteric mature newborns

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Full term newborns; with of age for more than 72 hours & serum bilirubin level more than 15 mg/dl. Exclusion criteria: All babies who received medication such as zinc sulphate & phenobarbital by mothers or newborn
Age
From **3 days** old to **28 days** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
-

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences Ethics Committee
Street address
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran Babol
City
Babol
Postal code
4717647745
Approval date
2016-08-22, 1395/06/01
Ethics committee reference number
MUBABOL,HRI.REC.1395.27

Health conditions studied

1

Description of health condition studied
Hyperbilirubinemia
ICD-10 code
P59.9
ICD-10 code description
Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description
Serum bilirubin's level
Timepoint
Total serum bilirubin level at the time of admission, daily during the hospitalization and at the time of the discharge
Method of measurement
Measuring of the total serum bilirubin level by biochemistry kits manufactured in Iran and by the method of spectrophotometry.

Secondary outcomes

1

Description
Serum zinc's level
Timepoint
At the time of admission and discharge
Method of measurement
Auto analyser

Intervention groups

1

Description
Administration of 5mg of zinc sulfate BD/per day in the treatment group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Children’s Hospital
Full name of responsible person
Dr Bahram Ranjbar
Street address
No 19, Amirkola Children’s Hospital, Amirkola, Babol, Mazandaran Province, IR Iran.
City
Amirkola, Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Full name of responsible person
Dr Ali Akbar Moghaddamnia

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Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran

City
Babol

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 Technology Affairs, Babol University of Medical Sciences

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
Amirkola Children’s Hospital

Full name of responsible person
Dr Bahram Ranjbar

Position
Pediatrician

Other areas of specialty/work

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Position
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Other areas of specialty/work

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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