

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

A survey of the efficacy of oral zinc sulfate on transcutaneous bilirubin in healthy term neonates

Protocol summary

Summary

The purpose of this study that will be done in Kermanshah Medical University is to evaluate the effect of oral zinc sulfate on transcutaneous bilirubin in healthy term neonates . The main inclusion criteria include: Term newborns with birth weight>2500, breast feeding and postnatal age less than 24 h of life. exclusion criteria : congenital anomaly, cephalhematoma .blood group incompatibility ,sepsis, formula feeding, exchange transfusion in previous sibling.The sample size include 124 neonates. whom are randomly assigned into two different groups.control group and treatment group . Normal care is give to the control group. treatment group, were given 5 mg of zinc sulfate daily till day fifth of age . In both group transcutaneous bilirubin level measured from the first day to the fifth day postnatally. The main outcome of this study was to see the effect of oral zinc sulfate , on the level of transcutaneous bilirubin.The neonates were checked for the frequency of stool.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110084961N4**

Registration date: **2013-05-20, 1392/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-20, 1392/02/30

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

Email address

homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-01-04, 1391/10/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey of the efficacy of oral zinc sulfate on transcutaneous bilirubin in healthy term neonates

Public title

A survey of the efficacy of oral zinc sulfate on transcutaneous bilirubin in healthy term neonates .

Purpose

Prevention

Inclusion/Exclusion criteria

The main inclusion criteria included:healthy term newborn with birth weight>2500, breast feeding and postnatal age less than 24 h. and exclusion criteria were : congenital anomaly, cephalhematoma.blood group incompatibility ,infection, formula feeding, exchange transfusion in previous sibling .

Age

To **1** year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

Street address

Building No=2, Shahid Beheshti Avenue, Kermanshah
University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2013-04-27, 1392/02/07

Ethics committee reference number

7/420/پ

Health conditions studied**1****Description of health condition studied**

Neonata I Hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes**1****Description**

Transcutaneous Bilirubin

Timepoint

Each 24h

Method of measurement

By Bilimeter

Secondary outcomes**1****Description**

Stool frequency

Timepoint

Each 24 h

Method of measurement

Inspection by Mother

Intervention groups**1****Description**

Newborns in the control group underwent routine daily care and transcutaneous bilirubin level measured (from the first day to the fifth day postnatal) daily .

Category

Prevention

2**Description**

Treatment group, were given 5 mg of zinc sulfate daily till day fifth of age . transcutaneous bilirubin level measured from the first day to the fifth day postnatally

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital, Kermanshah University of
Medical Sciences

Full name of responsible person

Homa Babaei

Street address**City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Deputy of Research, Kermanshah University of
Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

Neonatologist

Other areas of specialty/work

Street address

Department of Pediatrics, Imam Reza Hospital,
Kermanshah

City

Kermanshah

Postal code

6714415333

Phone

+98 83 1427 6303

Fax

Email

Homa_Babaei@kums.ac.ir Homa_Babaei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

Neonatologist

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Person responsible for updating data

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Web page address

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