

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

To evaluate the effect of Zinc sulfate on growth indexes and hepatitis B antibody titer in premature neonates

Protocol summary

Summary

The purpose of this investigation is to determine the effect of Zinc sulfate on growth indexes (weight, height, head circumference), and hepatitis B antibody titer in 28-36 week old premature neonates, born in Imam Reza and Motazedi hospitals of Kermanshah. In an incidental trial, 146 neonates having no organic disease and fed only by breast milk, were entered into the study. In case of the appearance of any sign of disease, they were excluded. The newborns were divided into two groups, case and control, in a totally random fashion. The former were given 3 ml of the Zinc sulfate containing 3 mg elemental Zinc, every day for 6 months, while the latter received nothing. The weight, height and head circumference of both groups were measured at birth and both were received hepatitis B vaccine. The growth and development indexes were checked every month in both groups. The hepatitis B vaccination was done routinely in both of them. The antibody titer and the indexes were evaluated one month after the vaccination done 6th month. The results were analyzed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010255008N1**

Registration date: **2010-11-21, 1389/08/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-21, 1389/08/30

Registrant information

Name

Shokoufe Ahmadipour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research affairs management of Kermanshah University of Medical Sciences

Expected recruitment start date

2010-10-07, 1389/07/15

Expected recruitment end date

2011-02-19, 1389/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of Zinc sulfate on growth indexes and hepatitis B antibody titer in premature neonates

Public title

To evaluate the effect of Zinc sulfate on growth indexes and hepatitis B antibody titer in premature neonates

Purpose

Diagnostic

Inclusion/Exclusion criteria

The inclusion criteria: 28-36 gestational age, lack of congenital or organic disease, breast feeding. The exclusion criteria: Formula feeding, congenital or organic disease, contracting any disease during study, taking Zinc sulfate irregularly.

Age
From **28 years** old to **36 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **146**

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
Shahid Beheshti Blvd.

City
Kermanshah

Postal code
67155-1469

Approval date
2010-10-05, 1389/07/13

Ethics committee reference number
420/6969/ 7/پ

Health conditions studied

1

Description of health condition studied
Zinc deficiency

ICD-10 code
E60

ICD-10 code description
Dietary zinc deficiency

Primary outcomes

1

Description
Weight

Timepoint
birth time and monthly

Method of measurement
Pan scale

2

Description
lenght

Timepoint
birth time and monthly

Method of measurement
lenght scale

3

Description
head Circumference

Timepoint
birth time and monthly

Method of measurement
meter

4

Description
Antibody titer

Timepoint
1 month after injection of hepatit B vaccin at six month after birth

Method of measurement
Elisa method

Secondary outcomes

empty

Intervention groups

1

Description
control group: nothing

Category
N/A

2

Description
case group: 3 mg of zinc sulfate, daily for 6 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonate part, Imam Reza Hospital

Full name of responsible person
Dr. Mitr Hemmati

Street address

University St., Shahid Shiroudi Blvd.

City

Kermanshah

2

Recruitment center

Name of recruitment center

Neonate part, Mo'tazedi Hospital

Full name of responsible person

Dr. Mitr Hemmati

Street address

Ferdousi Sq.

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research affairs management, Kermanshah
University of Medical Sciences

Full name of responsible person

Dr. Keyghobad Ghadiri

Street address

Shahid Beheshti Blvd.

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Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research affairs management, 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

Dr. Mitr Hemmati

Position

Assistant professor/M.D.

Other areas of specialty/work

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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