

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of zinc supplementation on the treatment of neonatal sepsis

Protocol summary

Study aim

To determine the effect of zinc on neonatal sepsis

Design

This was a randomized controlled clinical trial with parallel groups carried out in a single phase on 50 neonates with sepsis.

Settings and conduct

Neonates with sepsis admitted to Bandar Abbas Pediatric Hospital in 2018-2019 were evaluated. Parents were asked to sign an informed consent to participate in the study. Patients were divided into two groups (25 each, as explained in the sampling section). Subsequently dosing and side effects of the drugs were explained to the parents. Neonates were examined on a daily basis. On the 1st day, platelet count, CRP, and CBC diff were measured. In case of normal laboratory results (absence of sepsis), lab tests were repeated 24 hours later, and in case of abnormal results (presence of sepsis), lab tests were repeated after 48 hours and later based on patients' conditions. The antibiotic regimen was individualized according to every patient's clinical condition. Any change in this regimen was recorded. The acquired data were then entered into the SPSS software for statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: neonatal sepsis, gestational age >37 weeks, neonatal age <28 days, parents' informed consent
Exclusion criteria: important congenital anomalies, hypoxic ischemic encephalopathy, intracranial hemorrhage, respiratory distress syndrome, candidiasis

Intervention groups

In addition to antibiotics and if there were no contraindications for antibiotics, the intervention group received 1 mg/kg zinc gluconate manufactured by Alhawi (1 mg/ml) orally, via a nasogastric or orogastric tube, twice a day for one week. The control group only received antibiotics.

Main outcome variables

time to the improvement of symptoms, mortality,

hospital length of stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200810048347N1**

Registration date: **2020-12-11, 1399/09/21**

Registration timing: **retrospective**

Last update: **2020-12-11, 1399/09/21**

Update count: **0**

Registration date

2020-12-11, 1399/09/21

Registrant information

Name

Simin Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 5010

Email address

siminyazdi.hums@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-03-21, 1398/01/01

Trial completion date

2019-04-09, 1398/01/20

Scientific title

The effect of zinc supplementation on the treatment of neonatal sepsis

Public title

The role of zinc supplementation in neonatal sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of at least 2 clinical signs of sepsis including pallor or generalized jaundice, cardiovascular manifestations (tachy- or bradycardia, poor perfusion, or shock), change in body temperature (hypo- or hyperthermia), respiratory manifestations (grunting, intercostal retraction, apnea, or cyanosis), neurologic manifestations (hypotonia, lethargy, irritability, or seizure), gastrointestinal symptoms (abdominal distension, hepatosplenomegaly) CRP >5 mg/ml Presence of at least 1 positive serum parameter based on Fanarrof (book) including WBC <5000/microliter or >25000 at birth or WBC>30000 12-24 hours after birth or WBC>21000 on the second day of birth or the following days, absolute neutrophil count (ANC) <1800/microliter, platelet count <150000/microliter, immature/total (I/T) neutrophil ratio <0.16 on the first day and <0.13 from the second day on. Gestational age >37 weeks Age <28 days Informed consent of the parents

Exclusion criteria:

Important congenital anomalies such as trisomies Hypoxic ischemic encephalopathy Intracranial hemorrhage Respiratory distress syndrome Inborn errors of metabolism Candidiasis

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple randomization Unit of randomization: individual Tools of randomization: Randomization Main software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Technology and Research Vice-chancellery, East Side of Payambar Azam Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2019-02-17, 1397/11/28

Ethics committee reference number

IR.HUMS.REC.1397.301

Health conditions studied

1

Description of health condition studied

Neonatal sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

Mortality

Timepoint

At the end of the study

Method of measurement

Based on patient's medical chart

Secondary outcomes

1

Description

Time to improvement of clinical symptoms

Timepoint

At the end of the study

Method of measurement

Daily clinical examination

2

Description

Hospital length of stay
Timepoint
At the end of the study
Method of measurement
Based on the patient's clinical charts

Intervention groups

1

Description

Intervention group: the intervention group received 1 mg/kg zinc gluconate manufactured by Alhawi (1 mg/ml) orally, via a nasogastric or orogastric tube, twice a day for one week.

Category

Treatment - Drugs

2

Description

Control group: The control group only received antibiotics.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Pediatric Hospital

Full name of responsible person

Simin Yazdi

Street address

Bandar Abbas Pediatric Hospital, Imam Khomeini Blvd., Bandar Abbas

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siminyazdi.hums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Technology and Research Vice-chancellery,
Hormozgan University of Medical Sciences

Full name of responsible person

Nasrin Davari Dolatabadi

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Technology and Research Vice-chancellery, East Side
of Payambar Azam Hospital, Bandar Abbas

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n.davari@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Technology and Research Vice-chancellery, Hormozgan
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

Bandar Abbas Pediatric Hospital

Full name of responsible person

Simin Yazdi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data will be available after deidentification.

When the data will become available and for how long

Data will be available starting in 2021

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Eligible individuals will be able to use the data for pooled analysis.

From where data/document is obtainable

Via an email address: siminyazdi.hums@gmail.com to Dr. Simin Yazdi.

What processes are involved for a request to access data/document

Within a month of presenting a valid identification card

Comments