

# 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

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7366579158

##### Phone

+98 76 3366 6242

##### Email

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

##### Street address

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

#### City

Bandar Abbas

#### Province

Hormozgan

#### Postal code

7919915519

#### Phone

+98 76 3333 7379

#### Email

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

##### Street address

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

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7366579158

##### Phone

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##### Email

siminyazdi.hums@gmail.com

## Person responsible for scientific 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**  
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**Postal code**  
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siminyazdi.hums@gmail.com

## Person responsible for updating data

### 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**  
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**Street address**  
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**Postal code**  
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**Email**  
siminyazdi.hums@gmail.com

## 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