Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Oral Zinc on Reduction of Mortality in Newborns with Neonatal Sepsis

Protocol summary

Study aim
The Effect of Oral Zinc on Morbidity and Mortality in Neonatal Sepsis
Design
. Two arm parallel group randomised double blinded trial
Settings and conduct
The aim of this study was to evaluate the effect of oral zinc sulfate on mortality and morbidity in neonatal sepsis admitted to NICU of Shahrekord Hajar Hospital during 2016-2017. Parents of neonates and data analyzer and committee on safety and supervision of data were kept unaware of the groups their neonate was allocate to.
Participants/Inclusion and exclusion criteria
neonates with sepsis are enrolled and neonates with congenital anomaly ,GA<32 weeks, NEC excluded from trial
Intervention groups
The first group received the oral zinc sulfate for 10 days, together with the antibiotic therapy, and the second group (the control group) received the classic treatment of sepsis.
Main outcome variables
mortality morbidity Hospitalization period

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180915041040N2**
Registration date: **2019-08-16, 1398/05/25**
Registration timing: **retrospective**

Last update: **2019-08-16, 1398/05/25**
Update count: **0**
Registration date
2019-08-16, 1398/05/25

Registrant information
Name
Roya Choopani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-06-10, 1395/03/21
Expected recruitment end date
2017-10-02, 1396/07/10
Actual recruitment start date
2016-06-12, 1395/03/23
Actual recruitment end date
2017-08-23, 1396/06/01
Trial completion date
2017-11-12, 1396/08/21

Scientific title
The Effect of Oral Zinc on Reduction of Mortality in Newborns with Neonatal Sepsis

Public title
The Effect of Oral Zinc on Neonatal Sepsis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
neonate less than 28 day old neonate with sepsis
Exclusion criteria:
parental dissatisfaction threatening congenital anomalies asphyxia(resuscitation at birth more than 15 minutes or 10-minute Apgar score less than 5) Gestational age less than 32 weeks neonatal necrotizing enterocolitis

Age
From **1 day** old to **28 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Parents of neonates and data analyzer and committee on safety and supervision of data were kept unaware of the groups their neonate was allocate to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Hajar hospital,parastar street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815874119
Approval date
2017-05-29, 1396/03/08
Ethics committee reference number
IR.SKUMS.REC.1396.49

Health conditions studied

1

Description of health condition studied
neonatal sepsis
ICD-10 code
ICD-10 code description

2

Description of health condition studied
neonatal sepsis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mortality
Timepoint
Neonatal period
Method of measurement
Number

Secondary outcomes

1

Description
Hospitalization period
Timepoint
Neonatal period
Method of measurement
Day

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
Roya Choupani
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Hajar Hospital ,Parastar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr.Kamal Solati
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Kashani Street,
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+98 38 3334 2414
Email
vcrt@skums.ac.ir
Web page address
https://skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Roya.Choopani
Position
Associate Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There are no information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available