

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of intravenous immunoglobulin on reduction of sepsis mortality

Protocol summary

Summary

We study the effect of intra venous immunoglobulin (IVIG) on premature neonates with blood culture proven sepsis. Treatment with single dose 1gr IVIG plus antibiotics in 25 individuals of intervention group and treatment with antibiotics only in 25 individuals of control group will be done. Finally we compare the mortality between case and control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710301378N4**
Registration date: **2009-03-18, 1387/12/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-03-18, 1387/12/28

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

farhata@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2002-07-05, 1381/04/14

Expected recruitment end date

2003-07-05, 1382/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous immunoglobulin on reduction of sepsis mortality

Public title

Effect of intravenous immunoglobulin on reduction of sepsis mortality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preterm infants that have birth weight less than 2500gr with positive blood culture and admitted in NICU of Emamreza hospital. Exclusion criteria: Congenital anomaly, severe pulmonary problem or ventilation, cardiac disease, nephrologic problem

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice chancellor for research of Mashhad University of Medical Sciences

Street address

Ghoreshi bulding - Daneshgah street

City

Mashhad

Postal code**Approval date**

2003-10-08, 1382/07/16

Ethics committee reference number

1520-ب

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

neonate infection

ICD-10 code

P36.9

ICD-10 code description

Bacterial sepsis of newborn, unspecified

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

mortality

Timepoint

the end of study

Method of measurement

mortality rate

Secondary outcomes

empty

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

intervention group: 1000mg/K IVIG single dose + Routine antibiotic therapy

Category

Treatment - Drugs

2**Description**

control group: Routine antibiotic therapy

Category

Treatment - Drugs

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

NICU Emamreza hospital

Full name of responsible person

Dr.Ashraf mohammadzadeh

Street address

NICU- Emamreza hospital

City

Mashhad

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

Mashhad university of medical sciences

Full name of responsible person

Dr.jalil tavakol afshari

Street address

Ghoreshi bulding-Daneshgah street

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Neonatal Research Center

Full name of responsible person

Dr. Ahmadshah Farhat

Position

Neonatologist, assistant professor

Other areas of specialty/work**Street address**

NRC-NICU-Emamreza hospital

City

Mashhad

Postal code

9137913316

Phone

+98 51 1852 1121

Fax

+98 51 1852 5316

Email

farhata@mums.ac.ir

Web page address

www.mums.ac.ir/nrc

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Neonatal Research Center

Full name of responsible person

Dr. Ahmadshah Farhat

Position

Neonatologist, assistant professor

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Person responsible for updating data

Contact**Name of organization / entity**

Neonatal Research Center

Full name of responsible person

Dr. Ahmadshah Farhat

Position

Neonatologist, assistant professor

Other areas of specialty/work**Street address**

NRC-NICU-Emamreza hospital-mashhad-Iran

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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