

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of G-CSF efficacy in treatment of premature neonates with neutropenia and clinical sepsis

Protocol summary

Summary

In a randomized clinical trial , admitted premature neonates to NICU of Shahid Sadoughi Hospital , Yazd, Iran will be enrolled and randomly assigned to two groups. Laboratory tests including CBC, CRP, blood culture and urine culture will be performed for all participants at baseline and at the end of fourteenth day of the study. Both groups will be treated with the same antibiotics. In group I, subcutaneous GCSF in dosage of 10 µg / kg / day will be given for 5 consecutive days and the other group will receive normal saline subcutaneously. The neonates will be followed up for 14 days and respiratory status (oxygen dependency or need to mechanical ventilation), amount of tolerated feeding , occurrence of abdominal distension, side effects of injection, fever occurrence and its duration, thrombocytopenia, weight gain, confirmed documented sepsis by cultures and mortality will be evaluated in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303252639N11**

Registration date: **2013-04-04, 1392/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-04, 1392/01/15

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,

Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of G-CSF efficacy in treatment of premature neonates with neutropenia and clinical sepsis

Public title

G-CSF in treatment of premature neonates with neutropenia and clinical sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Gestational age of 30-37 weeks 2- Age of less than 10 days 3- Total neutrophil count $\leq$ 5000 in μ L 4- The neonate has sepsis based on clinical criteria Exclusion criteria: 1- Severe asphyxia 2- Life threatening congenital malformations 3- Total leukocytes count $\geq$ 20.000 in μ L 4- Intraventricular hemorrhage grade 3 or 4 5- Thrombocytopenia (platelets less than

150000 in μL) 6- Anemia (Hemoglobin $\leq$ 10g/dL) 7- Metabolic acidosis (PH $\leq$ 7.2)

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

Shahid Bamonar square

City

Yazd

Postal code**Approval date**

2012-09-05, 1391/06/15

Ethics committee reference number

119132

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

neonatal sepsis

ICD-10 code

B99

ICD-10 code description

Other infectious diseases

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

oxygen dependency

Timepoint

continuously

Method of measurement

pulse oximetry

2**Description**

need to mechanical ventilation

Timepoint

continuously

Method of measurement

pulse oximetry

3**Description**

amount of tolerated feeding

Timepoint

daily

Method of measurement

clinical exam

4**Description**

mortality

Timepoint

continuously

Method of measurement

clinical exam

5**Description**

side effects of injection

Timepoint

continuously

Method of measurement

clinical exam

Secondary outcomes**1****Description**

confirmed documented sepsis by cultures

Timepoint

at the end of fourteenth day of the study

Method of measurement

based on results of cultures

2**Description**

occurrence of abdominal distension

Timepoint

continuously

Method of measurement

clinical examination

3

Description

fever occurrence and its duration

Timepoint

continuously

Method of measurement

clinical examination

4

Description

thrombocytopenia

Timepoint

daily

Method of measurement

laboratory

Intervention groups

1

Description

subcutaneous GCSF in dosage of 10 µg / kg / day for 5 consecutive days

Category

Treatment - Drugs

2

Description

normal saline subcutaneously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Sadoughi Hospital

Full name of responsible person

Dr.Mostafa Froomandi

Street address**City**

Yazd

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Deputy for research of Shahid Sadoughi University of Medical Sciences , Yazd, Iran .

Full name of responsible person

Dr.Fatemah Ezoddini

Street address

Bahonar Square, Central Building of University

City

Yazd

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

Yes

Title of funding source

Deputy for research of Shahid Sadoughi University of Medical Sciences , Yazd, Iran .

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**

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr.Lila Borjian

Position

Assistant professor, neonatologist

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

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr.Mostafa Froomandi

Position

Pediatric resident

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

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd,
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Full name of responsible person
Dr.Mostafa Froomandi
Position
Pediatric resident
Other areas of specialty/work
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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