Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 ≤ 5000 in µL 4- The neonate has sepsis based on clinical criteria Exclusion criteria: 1- Severe asphyxia 2- Life threatening congenital malformations 3- Total leukocytes count ≥ 20.000 in µL 4- Intraventricular hemorrhage grade 3 or 4 5- Thrombocytopenia (platelets less than

150000 in µL) 6- Anemia (Hemoglobin≤10g/dL) 7- Metabolic acidosis (PH ≤ 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 Bahonar 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 oximetery

2

Description
need to mechanical ventilation

Timepoint
continuously

Method of measurement
pulse oximetery

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
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Assistant professor, neonatologist
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Person responsible for updating data

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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