Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of feeding tolerance in very low birth weight infants given enteral Granulocyte-Colony Stimulating Factor(G-CSF) compared to historical controlled group.

Protocol summary

Summary

We want to evaluate effect of enteral Granulocyte-Colony Stimulating Factor(G-CSF) on feeding tolerance in very low birth weight infants . This non- randomized clinical trial study performs on preterm infants (≤1500gr birth weight) without any major anomaly. Two groups of neonates include in the study by sequential admissions. In historical control group (n=220) the enteral feeding begin and advance with our unit's feeding policy. In trial group (n=73) the neonates so feed with unit's feeding policy and receive enteral G-CSF daily concurrent with feeding started and continue for 7 days. The following outcome data will record: duration of hospital stay; mortality; time to establish one-half, two-thirds, and full enteral feedings; duration of total parenteral nutrition ; time of weight gain started; the in rate of necrotizing enterocolitis ; and adverse effects of enteral feeding and treatment (vomiting, increased gastric residual, abdominal distention, diarrhea, bloody stool, skin rash)

General information

Acronym

(G-CSF): Granulocyte-Colony Stimulating Factor

IRCT registration information

IRCT registration number: **IRCT2016051427886N1**
Registration date: **2016-07-22, 1395/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-22, 1395/05/01

Registrant information

Name

Mahmoud Soltani

Name of organization / entity

Shahid Beheshti University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Neonatal Research Center , Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of feeding tolerance in very low birth weight infants given enteral Granulocyte-Colony Stimulating Factor(G-CSF) compared to historical controlled group.

Public title

Effect of enteral Granulocyte-Colony Stimulating Factor(G-CSF) in very low birth weight infants.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All preterm newborns with birth weight less than 1500 gram Exclusion criteria : Congenital anomalies of the gastrointestinal tract (such as

omphalocele, gastroschisis, tracheoesophageal fistula); Acquired GI disorders such as GI perforation , obstruction and necrotising enterocolitis; Other major anomalies such as congenital cyanotic heart disease, neural tube defect, diaphragmatic hernia and trisomy

Age
To **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **293**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Shahid Beheshti University of Medical Science

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Post code: 198396-3113

City
Tehran

Postal code

Approval date
2016-04-12, 1395/01/24

Ethics committee reference number
IR.SBMU.SM.REC.1395.12

Health conditions studied

1

Description of health condition studied
feeding tolerance in newborns

ICD-10 code
p92.9

ICD-10 code description
Feeding problem of newborn, unspecified

2

Description of health condition studied
Reactions due to drugs administered to newborn

ICD-10 code
p93

ICD-10 code description
Reactions and intoxications due to drugs administered to fetus and newborn

Primary outcomes

1

Description
feeding tolerance

Timepoint
since start of feeding until full feeding

Method of measurement
ml/kg/day

Secondary outcomes

1

Description
hospital stay duration

Timepoint
since birth day to discharge date

Method of measurement
hospitalized date

2

Description
duration of parenteral nutrition

Timepoint
since birth day to discotinue parenteral nutrition

Method of measurement
parenteral nutrition dates

3

Description
antibiotic use

Timepoint
daily

Method of measurement
antibiotic use dates

4

Description
rate of necrotizing enterocolitis

Timepoint
daily

Method of measurement
times of occurance

5

Description
death

Timepoint
daily
Method of measurement
numbers of occurance

Intervention groups

1

Description
The 73 included newborns in trial group receive enteral G-CSF. These neonates feed with the unit's feeding policy and receive a single daily dose of enteral G-CSF, 5 micg/kg (Filgrastim 300 micg/.5mL) concurrent with feeding started. The daily dose for each patient dilutes in sterile distilled water and administrates through the orogastric/nasogastric tube with milk feedings for 7 days. The unit's feeding policy is same as historical control group including to start early trophic feeding with 10-20 mL/kg/day and progress by 10-20 mL/kg/day for as long as tolerate.
Category
Treatment - Drugs

2

Description
In historical control group (n=220) the enteral feeding begin and advance with our unit's feeding policy. Our unit's feeding policy is to start early trophic feeding with 10-20 mL/kg/day, preferably breast milk if available, and progress by 10-20 mL/kg/day for as long as tolerate (as judge by the attending neonatologist). This feeding policy don't alter during this study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Dr. Seyed Abolfazl Afjeh
Street address
Fadaian Islam St
City
Tehran

2

Recruitment center
Name of recruitment center
Mofid Children Hospital
Full name of responsible person
Dr, Seyed Hossein Fakhraee
Street address
Shariati St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neonatal Research Center
Full name of responsible person
Dr. Mohammad Kazemian
Street address
Mofid Children Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neonatal Research Center
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 Beheshti University of Medical Science
Full name of responsible person
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Position
Attend
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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