# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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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Iran (Islamic Republic of)

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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**
Dr. Seyed Abolfazl Afjeh
**Position**
Attend
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## Person responsible for scientific inquiries

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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*