Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of Granulocyte-Colony Stimulating Factor on feeding tolerance in preterm infants

Protocol summary

Study aim
Comparison of Granulocyte-Colony Stimulating Factor and Erythropoietin by gastric gavage on feeding tolerance in preterm infants

Design
A clinical trial with an intervention group and a control group with 68 samples, one blind, randomized.

Settings and conduct
This study is conducted in the NICU section of the Ayatollah Rouhani Hospital in Babol. These neonatal are divided into two groups (each group of 34 neonate) as follows: When supplementing with the order of the neonatal physician, the supplementary supplement is also prescribed on medical instructions:The first group (intervention) received oral filtration (G-CSF) and the second group (control) received no intervention. The dose of this medicine is as follows: Oral Filtration Oral Ampoule 4/5 micrograms per kg body weight, daily, divided in two steps via gastric gavage. The above medicine starts with intestinal nutrition and is discontinued after a maximum of 10 days. The G-CSF vial is 300 micrograms or 30 million units Neupogen filgrastim) manufactured by Amgen in the Netherlands. Group assignment by random method, which will be determined by the statistician by using computer software pre-defined by the statistician and will be given by the nurse by installing the same labels A and B, and only the infants who are in This patient study is presented for the purpose of acquiring a blinded drug.

Participants/Inclusion and exclusion criteria
Preterm neonate with a gestational age of less than 32 weeks and a birth-weight less than or equal to 1200 gr

Intervention groups
Administration of Oral Filgrastim (G-CSF) in the intervention group to assess the increase in feeding tolerance in preterm infants.control group will not receive any medication

Main outcome variables
Primary outcome: incidence of intolerance to nutrition; time to reach the maximum milk yield. (100 cc/kg/day) (full feed) Secondary outcomes: The time to start weighting; the length of stay in the hospital.

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20180731040650N1**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-04, 1397/12/13**
Update count: **0**

Registration date
2019-03-04, 1397/12/13

Registrant information

Name
Zahra akbarian Rad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3234 6963

Email address
zhr_akbarian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-21, 1397/06/30

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Granulocyte-Colony Stimulating Factor on feeding tolerance in preterm infants

Public title
Effect of Granulocyte-Colony Stimulating Factor on feeding tolerance in preterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm neonate Gestational age of less than 32 weeks Birth-weight less than or equal to 1200 gr
Exclusion criteria:
Incidence of necrotizing enterocolitis Sepsis Shock Intravenous hemorrhage (IVH) Grade 2 Disease that requires an oral medication (except vitamins and supplements) severe and at-risk diseases
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
The assignment of the groups is randomized, with the prior number of the three groups using the computer software specified by the statistician and given the same labels A, B and C on the envelopes by the nurse, and only the newborns Which are presented in this patient study for the purpose of acquiring a blinded drug; therefore, a blinded one is considered.
Blinding (investigator's opinion)
Single blinded
Blinding description
Group assignment by random method, which will be determined by the statistician by using computer software pre-defined by the statistician and will be given by the nurse by installing the same labels A and B, and only the infants who are in This patient study is presented for the purpose of acquiring a blinded drug; therefore, a blind spot is considered.
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
Ganjafroz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2018-09-18, 1397/06/27
Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.135

Health conditions studied

1

Description of health condition studied
Preterm infants
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Incidence of intolerance to nutrition
Timepoint
Daily
Method of measurement
check list

2

Description
Time to reach the full feed
Timepoint
Daily
Method of measurement
check list

Secondary outcomes

1

Description
Time to start weighting

Timepoint
Time to start weighting
Method of measurement
Check list

2

Description
Duration of stay in hospital
Timepoint
Discharge time
Method of measurement
Check list

Intervention groups

1

Description
Intervention group 1: Oral filgrastim ingestion starts at 4/5 micro grams per kilogram of body weight, daily, with the onset of intestinal nutrition, and is discontinued after a maximum of 10 days.
Category
Treatment - Drugs

2

Description
Control group: Infants receive only breast milk at a specified rate.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Dr Elham Farahanian
Street address
Ganj Afroz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3223 8301
Fax
+98 11 3223 8309
Email
info@mubabol.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
Street address
Babol University of Medical Sciences, Ganjafroz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 4727
Fax
+98 11 3219 9591
Email
info@mubabol.ac.ir
Web page address
http://research.mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Zahra Akbarian Rad
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ganj Afrouz Avenue
City
Babol
Province
Mazandaran
Postal code
4717647745

Phone
+98 11 3223 8301
Fax
+98 11 3223 8309
Email
Zhr_akbarian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Zahra Akbarian
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ganj Afrouz Avenue, Ayatollah Rouhani Hospital
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 32238031
Fax
+98 11 3223 8039
Email
zhr_akbarian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Zahra Akbarian
Position
Associated Proffesor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ganj Afrouz Avenue
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3223 3809
Fax
+98 11 3223 8309
Email
Zhr_akbarian@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available