Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of Enteral Recombinant Erythropoietin(R-EPO) in prevention of Necrotizing Entrocolits in Very Low Birth Weight infants

Protocol summary

Summary

The aim of the study is evaluation of the Enteral Recombinant Erythropoietin(rEpo) in prevention of Necrotizing Entrocolits(NEC) in premature infants. Preterm infants who are inborn with gestational age 28 weeks or less or Birth weight 1250 gram or less and they are Appropriate for Gestational Age, without any major congenital anomaly will be recruited. After receiving the consent of the parents the patients will be divided randomly in 3 groups. Two groups of preterm infants consisting of 35 in each group will receive 5mL enterally of the study solution (synthetic Amniotic Fluid)/kg/day divided into 3dosing. Case group (Group 1) will receive the fluid containing rEpo . Another group(Group2) will receive the solution without rEpo . The fluid will be started after3 days of birth and will continue until 3 weeks. They will also receive feeding with breast milk after giving the fluid .In 35 of the preterm infants as Control group breast milk will start and increase according the routine guideline of the unit without any solution .The patients in 3 groups will follow until discharge or death and compare to frequency of NEC or mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310164113N4**
Registration date: **2014-02-07, 1392/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-07, 1392/11/18

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz Universisty of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

hossainm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Pediatric Health Research center of Tabriz

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Enteral Recombinant Erythropoietin(R-EPO) in prevention of Necrotizing Entrocolits in Very Low Birth Weight infants

Public title

Evaluation of Enteral Erythropoietin in prevention of Necrotizing Entrocolits in Very Low Birth Weight infants

Purpose

Prevention

Inclusion/Exclusion criteria

Patients will eligible if they are inborn preterm infants with gestational age of 28 weeks or less or Birth weight 1250 gram or less and they are Appropriate for Gestational Age. Patients will consider ineligible if they

have any congenital anomaly of the gastrointestinal tract (i.e., omphalocele, gastroschisis, tracheoesophageal fistula, intestinal perforation), or have other major congenital anomalies (congenital heart disease, neural tube defect, congenital diaphragmatic hernia, Trisomy, etc.).They Also will exclude if the neonates judge as being too ill to be acceptable study candidates; this criterion will set as receiving mechanical ventilation with an FIO2>0.60

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sceinces

Street address
Central building 2, Golgasht Street, Research and Technology Department of Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2013-11-18, 1392/08/27

Ethics committee reference number
92120

Health conditions studied

1

Description of health condition studied
Necrotizing Enterocolitis of fetus and neonate

ICD-10 code
p77

ICD-10 code description
Necrotizing Enterocolitis of fetus and neonate

Primary outcomes

1

Description
Frequency of Necrotizing Enterocolitis

Timepoint
After third days of birth until discharge from hospital or death

Method of measurement
Clinical evaluation and radiologic finding

2

Description
Mortality rate

Timepoint
After third days of birth until discharge from hospital or death

Method of measurement
Clinical evaluation

3

Description
tolerance data included the occurrence of emesis, gastric residuals, diarrhea, bloody stools, abdominal distention

Timepoint
After third days of birth until discharge from hospital or death

Method of measurement
Clinical evaluaion and measurement of abdominal circumference)

Secondary outcomes

1

Description
Frequency of Retinopathy Of Prematurity

Timepoint
After 4 weeks of birth

Method of measurement
Ophtalmologic exam by Retinologist

2

Description
Frequency of Chronic Lung Disease

Timepoint
After 28 days of birth

Method of measurement
Clinical evaluation of needs of oxygen or respratory support

3

Description

Frequency of Intraventricular Hemorrage (IVH)

Timepoint

After one mounths of age

Method of measurement

Ultrasonography by radiologist

Intervention groups

1

Description

In Control group of the patients breast milk will be started and increase according the routine guideline of the unit without any solutions

Category

Treatment - Drugs

2

Description

The first group of the (case) patients will receive the synthetic Amniotic fluid solution with Recombinant Erythropoietin(r-EPO) . The hospital pharmacist will make the solution using sterile technique and The solution contained contains ; 115 meq/l sodium chloride, 17 meq/L sodium acetate, and 4 meq/l potassium chloride,4400 mU/ml Epoetin alfa (Epogen, Amgen). Human serum albumin (5%) will be added to the infusion bag prior to the addition of the rEPO (final concentration of albumin=0.05%). The fluid contain a 10-fold higher concentration of Epo than natural amniotic fluid . Aliquots (10 ml) will be frozen until use. Solution in the syringe will be pushed through the orogastric tube prior to insertion into the patient in order to reduce binding of rEpo to the plastic tubing. Upon enrollment of a subject a full day's dose will thawed. The full day's dose (5 Ml/Kg/D will then be divided into 3 equal amounts, to be administered by the bedside nurse every 8 hours. Each aliquot will allow warming to room temperature before it will administer. They will also receive feeding with breast milk after giving the fluid. The nurse of the patient and the person who are responsible for data collection will be blind to the group of the patients and the solutions.

Category

Treatment - Drugs

3

Description

The second group of the(case) patients will receive the synthetic Amniotic fluid solution without Recombinant Erythropoietin(r-EPO) . The hospital pharmacist will make the solution using sterile technique and The solution contained contains ; 115 meq/l sodium chloride, 17 meq/L sodium acetate, and 4 meq/l potassium chloride. Human serum albumin (5%) will be added to the infusion bag (final concentration of albumin=0.05%). Aliquots (10 ml) will be frozen until use. Solution in the syringe will be pushed through the orogastric tube prior to insertion into the patient in order to reduce binding of rEpo to the plastic tubing. Upon enrollment of a subject a full day's dose will be thawed. The full day's dose (5 Ml/Kg/D) will then be divided into 3 equal amounts, to be administered by the bedside nurse every 8 hours. Each aliquot will allow warming to room temperature before it will administer. They will also receive feeding with breast milk after giving the fluid. The nurse of the patient and the person who are responsible for data collection will be blind to the group of the patients and the solutions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Dr. Mohammad Bagher Hosseini

Street address

Artesh street.Azadei Ave

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric Health Research Center of Tabriz University of Medical Sceinces

Full name of responsible person

Dr.Mohammad Barzegar

Street address

Children Hospital

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pediatric Health Research Center of Tabriz University of Medical Sceinces

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

Tabriz University of Medical Sceinces
Full name of responsible person
Dr.Mohammad Bagher Hosseini
Position
Associate Professor
Other areas of specialty/work
Street address
Alzahra Teaching Hospital,Neonatal Unit
City
Tabriz
Postal code
Phone
+98 41 1335 0357
Fax
Email
hosseini_mb@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University Of Medical Sceinces
Full name of responsible person
Dr.Mohammad Bagher Hosseini
Position
Associate Professor
Other areas of specialty/work
Street address
Alzahra teaching Hospital,Neonatal Unit
City
Tabriz
Postal code
Phone
+98 41 1335 0357
Fax
Email
hosseini_mb@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sceinces
Full name of responsible person
Dr.Mohammad Bagher Hosseini
Position
Associate Professor
Other areas of specialty/work
Street address
Alzahra Teaching Hospital,Neonatal Unit
City
Tabriz
Postal code
Phone
+98 41 1335 0357
Fax
Email
hosseini_mb@yahoo.com
Web page address

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