Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

comparison of intravenous v/s enteral administration of fat emulsion in very low birth weight infants

Protocol summary

Summary

The aim of this study is evaluation of short term prognosis of enteral administration of fat emulsion (20% Esmoff) in very low birth weight infants.Three hundred and frothy five Very Low Birth Weight infants with birth weight of 700-1499 will be included.The Patients with negative blood culture in 48 hours of age will be chosen during 3 -5th days of birth.They will be divided randomly in three groups. One group of the patients will be received fat emulsion 20% (Esmof)between 3-5 days of age by intravenous route. Another group(case) will by receive by eternal form with same dose .Control group will not receive any type of fat emulsion. The dose of fat emulsion will be 1 gr/Kg/d and increase step by step to 3 gr/Kg/d . Daily wight gain ,increase of head circumference per week ,frequency of necrotizsing enterocolitis with grade 2 or more and mortality will be compare in 3 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310164113N5**
Registration date: **2015-08-01, 1394/05/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Pediatric health research center of Tabriz University Of Medical Sceinces

Expected recruitment start date

2015-06-26, 1394/04/05

Expected recruitment end date

2015-12-26, 1394/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of intravenous v/s enteral administration of fat emulsion in very low birth weight infants

Public title

Evaluation of enteral administration of fat in very low birth weight infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Inborn Very Low Birth Weight infants in Alzahra Teaching Hospital; Birth Weight between 700-1499 gram; Appropriate for Gestational Age; without proven sepsis Exclusion Criteria : first blood culture positive(during 48 hours); Major congenital Anomalies; Nercotizing Entrocolitis; Direct Hyperbilirubinemia(Direct Bilirubin more than 2 Mg/dl and more than 15% of total Bilirubin); Sever heart failure need treatment or Shock

Age

From **3 days** old to **3 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University Of Medical Sceinces

Street address

Reseaech and Tecnology Chancelllor, Buidling 2, Golgasht St

City

Tabriz

Postal code

Approval date

2015-05-25, 1394/03/04

Ethics committee reference number

TBZMED.REC.1394.172

Health conditions studied

1

Description of health condition studied

prematurity

ICD-10 code

P07.2

ICD-10 code description

Less than 28 completed weeks (less than 196 completed days) of gestation.

Primary outcomes

1

Description

daily weight gain

Timepoint

From 3-5 days until3 weeks

Method of measurement

A digital scale with 1 gr sensivity

2

Description

Frequency of Necrotizing enterocolitis

Timepoint

From 3-5 days until discharge from hospital

Method of measurement

Aspirate more than 30% of previus feeding and the circomference of the belly more than 2 Cm with raidiologic findding

3

Description

Mortality rate

Timepoint

From 3-5 days until discharge from hospital

Method of measurement

evaluation of heart rate and respiration

4

Description

head circomference

Timepoint

From 3-5 days until discharge from hospital

Method of measurement

use of plastic tape with 1 CM accuracy

Secondary outcomes

1

Description

Frequency of proven sepsis

Timepoint

From 3-5 days until discharge from hospital

Method of measurement

Evaluation of clinical sign and CBC and CRP and Blood Culture

2

Description

Mean of serum triglycerid

Timepoint

From 3-5 days until 3 weeks

Method of measurement

mesuring serum triglycerid level by Selectra machin

3

Description

Frequency of feeding intolerance

Timepoint

From 3-5 days until 3 weeks

Method of measurement

Evaluation of GI aspitate before each feeding and finding more than 30% of previus one

4

Description
Frequency of Chronic Lung Disease
Timepoint
From 28 days until discharge from hospital
Method of measurement
Need of Oxygen or ventilatoey support

5

Description
Frequency of Retinopathy Of Prematurity
Timepoint
From 28 days until discharge from hospital
Method of measurement
Examination of the retin by indirect Retinoscopy

6

Description
Mean of hospitalization
Timepoint
From 3-5 days until discharge from hospital
Method of measurement
hospitalization recording sheet

7

Description
Frequency of Cholestasis
Timepoint
From 3-5 days until discharge from hospital
Method of measurement
Evaluation of Direct and Indirect Bilirubin level by Selectra Machin

Intervention groups

1

Description
In intervention group after tolerating the Minimal enteral feeding of breast milk we will start fat emulsion (Esmof20%) enteraly. Dose of Fat will be 1 gr/kg/d and will be increased step by step to 3 gr/kg/d.
Category
Treatment - Drugs

2

Description
In control group Fat emulsion will be given by intravenous rout. Dose of Fat will be 1 gr/kg/d and will be increased step by step to 3 gr/kg/d.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Teaching Hospital
Full name of responsible person
MohammadBagher Hosseini
Street address
Alzahra Hospital, Artesh Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Peiatric Health Research Center of Tabriz
Full name of responsible person
Mohammad Barzegar
Street address
Children Hospitalof Tabriz, Sheshgelan Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Peiatric Health Research Center of Tabriz
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
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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