

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 fifty 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 be receive by enteral 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 weight gain, increase of head circumference per week, frequency of necrotizing 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

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Pediatric health research center of Tabriz University Of Medical Sciences

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; Necrotizing Enteroocolitis; 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 Sciences

Street address

Reseaech and Tecnology Chancellor, Buidling 2, Goltasht 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 until 3 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 previous feeding and the circumference of the belly more than 2 Cm with radiologic finding

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 circumference

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

measuring 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 aspirate before each feeding and finding more than 30% of previous 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%) enterally. 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, Sheshgela 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

Full name of responsible person

Mohammad Bagher Hosseini

Position

Associate Professor

Other areas of specialty/work

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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