

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Adverse early Outcomes of Prolonged Initial Empirical Antibiotic Therapy in VLBW Premature Infants

Protocol summary

Summary

For 150 Very Low Birth Weight (VLBW) infants who are inborn we will send: Blood culture(B/C) with Bacteck method , CBC diff and CRP at the admission . According to the current protocol of hospital empirical Antibiotics will be started too. After 3-5 days with receiving the B/C results ,a CRP will be sent .After receiving the consent of the parents the patients will be divided in two groups. Control group will continued the empirical Antibiotics until the patients have Iv access, in case group antibiotics will be discontinued if the results of B/C and CRP would be negative and clinical condition would not suggestive of infection. The patients will be followed until discharge or death .Early outcomes consist of: Death, Discharge or transport to other centers , Narcotizing Entrocholits(stage 2 or more) will be compared in two groups. Total days of Antibiotic therapy , duration of hospitalization and bacteriologic data will also be compared..

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210124113N3**

Registration date: **2014-04-24, 1393/02/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-24, 1393/02/04

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

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Recruitment status

Recruitment complete

Funding source

Pediatric Health Research center of Tabriz University of Medical Sciences

Expected recruitment start date

2013-11-01, 1392/08/10

Expected recruitment end date

2014-11-01, 1393/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Adverse early Outcomes of Prolonged Initial Empirical Antibiotic Therapy in VLBW Premature Infants

Public title

Evaluation of Adverse early Outcomes of Prolonged Initial Empirical Antibiotic Therapy in Premature Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inborn preterm infants in Alzahra Teaching hospital of Tabriz Without congenital Anomaleis Very Low Birth weight (VLBW): Birth Weight 1499 and less Admit in 72 hours of life for respiratory Distress or R/O Sepsis

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Research and Technology Department of university

City

Tabriz

Postal code

Approval date

2013-10-20, 1392/07/28

Ethics committee reference number

92130

Health conditions studied

1

Description of health condition studied

Very Low Birth Weight infants

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight

Primary outcomes

1

Description

Nosocomial Infection

Timepoint

from 72 hours of life until Discharge

Method of measurement

Positive blood culture with clinical symptoms

2

Description

Mortality

Timepoint

From admission time until discharge or death time

Method of measurement

Evaluation and registration form of hospital

3

Description

Necrotizing Enterocolitis (stage 2 or more)

Timepoint

after the day 5 until discharge

Method of measurement

gastrointestinal symptoms and radiologic evidence

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

from the admission time until discharge

Method of measurement

Registration Form (Medical records of the patient)

2

Description

Total days of Antibiotic therapy

Timepoint

From the first day of admission until discharge

Method of measurement

Registration form (Medical records of the patient as days)

3

Description

Chronic Lung Disease

Timepoint

Need of Oxygen or Respiratory support more than 28 days after birth

Method of measurement

Registration form (Medical records of the patient)

4

Description

Intraventricular Hemorrhage (Grade 2 or more)

Timepoint

7-10 days after birth

Method of measurement

Brain Sonography

Intervention groups

1

Description

In Control group after starting the empirical Antibiotics at the time of admission they will be continued until the patients have lv access

Category

Treatment - Drugs

2

Description

in case group after starting the empirical Antibiotics at the time of admission they will be discontinued after 3-5 days if the results of B/C and CRP would be negative and clinical condition would not suggestive of infection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital of Tabriz

Full name of responsible person

Mohammad Bagher Hosseini MD

Street address

Alzahra Teaching Hospital,Artesh Street

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 of Tabriz

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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*