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 Universisty of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Pediatric Health Research center of Tabriz University of Medical Sceinces

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 Tabrriz University of Medical Sceinces
Street address
Research and Technology Deprtment 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 admision time until discharge or death time
Method of measurement
Evaluation ang registration form of hospital

3

Description
Necrotizing Entrocolitis (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 admition 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 Hemorrage (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 Iv 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 updating data

Contact

Name of organization / entity

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Full name of responsible person

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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