

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Early outcome of Extremely Low Birth Weight Infants before and after Establishment of Palliative Care protocol according to Clinical Risk Index for Babies scoring system (CRIB II)

Protocol summary

Study aim

- 1- Establishment of the palliative care protocol for extremely low birth weight (ELBW) infants with Clinical Risk Index for Babies II (CRIB II) score more than 15
- 2- Determining of CRIB II for ELBW infants
- 3 - Evaluation of short-term outcome in ELBW infants

Design

Two arm parallel-group, double-blinded non-randomized trial

Settings and conduct

Preterm ELBW infants hospitalized in the newborn intensive care unit (NICU) of Tabriz Alzahra Hospital who have CRIB II scores more than 15 will receive palliative care including thermal support, intravenous fluid therapy, and respiratory support. The control group will also receive mechanical ventilation and surfactant therapy. The Infants of both groups will be followed until discharge and the outcomes of the groups will be compared. Nurses and the analyzer of data will not aware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preterm infants with the gestational age of 24/+0 to 26/+6 weeks and birth weight of 500 to 750 grams born in Tabriz Alzahra Hospital. Exclusion criteria: Preterm Infants who will be deceased in delivery or operation rooms, with major anomalies or major birth defects, gestational age less than 23 weeks and 6 days or more than 27 weeks, birth weight more than 750 grams

Intervention groups

Preterm ELBW infants with CRIB II score more than 15 will receive palliative care including thermal support, intravenous fluid therapy, and respiratory support. The control group will also receive mechanical ventilation and surfactant therapy.

Main outcome variables

Short-term outcome including mortality rate; necrotizing

enterocolitis grade 2 or more; retinopathy of prematurity; cerebral hemorrhage with grade 2 or more

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100607004113N18**

Registration date: **2020-04-18, 1399/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-18, 1399/01/30**

Update count: **0**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early outcome of Extremely Low Birth Weight Infants before and after Establishment of Palliative Care protocol according to Clinical Risk Index for Babies scoring system (CRIB II)

Public title

Effect of Palliative Care protocol on mortality and morbidity of Extremely Low Birth Weight Infants

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Extremely Low Birth Weight preterm infants with gestational age of (24 weeks+0 Day) to (26 weeks+6 Days) Birth weight between 500- 750 grams Inborn and admitted in Neonatal Intensive Care Unit of Alzahra teaching hospital of Tabriz

Exclusion criteria:

Born after assisted reproductive technology or In vitro fertilization (IVF) Infants born with major anomalies or birth defects Gestational age less than 24 Weeks or more than 27 weeks of gestation Infants who's parents aren't agreed with palliative care

AgeFrom **1 day** old to **1 day** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

research nurse who are blinded to groups . Analyzer of the data also will be blind to the groups of infants

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

Goltasht street

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Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.TBZMED.REC.1398.1070

Health conditions studied**1****Description of health condition studied**

Extreme immaturity of newborn

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mortality of ELBW neonate before and after Establishment of palliative care protocol according to (CRIB II) scoring system

Timepoint

From birth to discharge from hospital or death

Method of measurement

Questioner and evaluation of vital sign

Secondary outcomes**1****Description**

Necrotizing enterocolitis (NEC) satge 2 or more

Timepoint

From birth until discharge from hospital

Method of measurement

Questioner and Bell's stage

2**Description**

Retinopathy of Prematurity need intervention (Photocoagulation or Evastin injection)

Timepoint

From 28 days after birth until discharge from hospital

Method of measurement

Questioner and Revised International Classification of ROP (ICROP)

3

Description

Intraventricular Hemorrhage Grade 2 or more

Timepoint

During first week of life

Method of measurement

Brain ultrasonography

Intervention groups

1

Description

Preterm infants in two parallel groups include in the non randomized study , Intervention group are infants who have score of 15 or more according to Clinical Risk Index for Babies scoring system (CRIB II) .After consent of the parents This group of patients will receive palliative care consist of :thermal stabilization ,respiratory support as Nasal Continues Positive Airway Pressure , use of intravenous antibiotics consist of Ampicillin and Gentamicin(according to the guideline of the unit) and Total Parenteral Nutrition.

Category

Other

2

Description

Control group: are preterm infants who have score of less than 15 according (CRIB II)scoring system .This group of infants will receive full support care consist of : thermal stabilization ,respiratory support as Nasal Continues Positive Airway Pressure and Mechanical ventilation if needed , use of intravenous antibiotics consist of Ampicillin and Gentamicin(according to the guideline of the unit) , Total Parenteral Nutrition and Surfactant therapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra teaching hospital of Tabriz

Full name of responsible person

MohammadBagher Hosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammadbagher Hosseini

Position

Associate Professor of Pediatric Departement

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

This study is in the first steps and may be repeated in other centers without ethical considerations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available