

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Investigating the effect of trophic nutrition on the length of hospitalization and weight of low birth weight infants at discharge time in the Neonatal Intensive Care Unit.

Protocol summary

Study aim

Determining the effect of trophic nutrition on the duration of hospitalization and the weight at the time of discharge of low birth weight infants in the neonatal intensive care unit

Design

Clinical trial, with control and test group, without blinding, randomized by block method

Settings and conduct

It is an experimental interventional study with a block randomization method in the neonatal intensive care unit of Shahid Sadoughi Hospital, Yazd.

Participants/Inclusion and exclusion criteria

Entry requirements: Nonates weighing 1000-2000 grams at birth Fetal age 26 weeks to 36 weeks and 6 days (based on the first day of the mother's last period and early pregnancy ultrasound) Non-entry conditions: Neonates with major congenital anomalies Neonates with severe asphyxia Infants referred from other hospitals Infants with cardiac and metabolic disease

Intervention groups

Intervention group: low birth weight Neonates for whom trophic nutrition is started in the first 72 hours after birth along with intravenous nutrition (by a specialist doctor).

Main outcome variables

The length of hospitalization of low birth weight neonates
- Discharge weight of low birth weight neonates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231016059743N1**

Registration date: **2023-11-27, 1402/09/06**

Registration timing: **prospective**

Last update: **2023-11-27, 1402/09/06**

Update count: **0**

Registration date

2023-11-27, 1402/09/06

Registrant information

Name

Abolfazl Azarmi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3366 5225

Email address

a.azarmi@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of trophic nutrition on the length of hospitalization and weight of low birth weight infants at discharge time in the Neonatal Intensive Care Unit.

Public title

Investigating the effect of trophic nutrition on the length of hospitalization and weight of low birth weight infants at discharge time.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates weighing 1000-2000 grams at birth Fetal age 26 weeks to 36 weeks and 6 days (based on the first day of the mother's last period and early pregnancy ultrasound)

Exclusion criteria:

Neonates with major congenital anomalies Neonates with severe asphyxia Neonates referred from other hospitals Neonates with cardiac and metabolic disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

60 infants eligible for the study will be placed in two groups of 30 people. In order to randomly assign and ensure the balance of the number of people in the groups, the block randomization method will be used. In this study, blocks of four are used, where half of the people in each block are placed in one group and the other half in another group.

Blinding (investigator's opinion)

Not 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 Yazd University of Medical Sciences

Street address

شهر یزد، صفائیه، خیابان بوعلی، پژوهشکده علوم تولیدمثل یزد

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.SSU.REC.1402.065

Health conditions studied

1

Description of health condition studied

Necrotizing enterocolitis-premature osteopenia-neonatal sepsis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of hospitalization in low birth weight infants- discharge weight in low birth weight infants

Timepoint

From the time of admission to the discharge of low birth weight babies in the neonatal intensive care unit

Method of measurement

In order to measure the baby's weight at the time of discharge, we will use the scale available in the neonatal intensive care unit, which is of the zyklusmed brand (made in Iran under a German license). In order to determine the accuracy of the weight, its standard of accuracy will be checked by a 1 kg weight. In order to determine the reliability of the weight, it has been done through independent and repeated measurements, in other words, the researcher has weighed a patient several times with the same weight, and if the resulting numbers are equal, it is the reason that the weight has the necessary reliability.

Secondary outcomes

1

Description

Frequency of neonatal sepsis in low birth weight babies - Frequency of necrotizing enterocolitis in low birth weight neonates- Frequency of premature osteopenia in low birth weight neonates

Timepoint

From the time of admission to the discharge of low birth weight babies in the neonatal intensive care unit

Method of measurement

The criterion of sepsis is a positive blood culture by the BACTEC method (a product of America, Becton Dickinson company) when 3 cc of blood is taken from the neonate and sent to the laboratory of Shahid Sadoughi Hospital in Yazd, necrotizing enterocolitis is also based on Clinical criteria (abdominal distension, apnea, milk intolerance and residue) and paraclinical criteria (abdominal imaging) are defined. Prematurity osteopenia is also based on phosphorus index less than 4 and alkaline phosphatase more than 900 at 28 days of birth. which is

determined during a blood test taken from the baby.

Intervention groups

1

Description

Intervention group: low birth weight babies who receive trophic nutrition along with routine intravenous feeding in the neonatal intensive care unit.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd city

Full name of responsible person

Dr. Seyed Reza Mirjalili

Street address

Yazd City - Shahid Qandi Blvd. - Ibn Sina Blvd

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Email

sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Seyed Reza Mirjalili

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3724 0171

Email

info@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Seyed Reza Mirjalili

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Palestine Blvd., Lale St., Yasman Alley, 8

City

Yazd

Province

Yazd

Postal code

8915167367

Phone

+98 35 3830 1039

Email

dr_sr_mirjalili@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Seyed Reza Mirjalili

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Palestine Boulevard-Laleh Alley-Yasman Alley 8

City

Yazd

Province

Yazd

Postal code

8915167367

Phone

+98 35 3830 1039

Email

dr_sr_mirjalili@yahoo.com

+98 31 3366 5225

Email

A.azarmi@stu.ssu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Abolfazl Azarmi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Eastern Madani St., in front of Ardibehesht
Kindergarten, No. 133

City

Khomeini shahr

Province

Isfahan

Postal code

8415665511

Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available