

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the effect of two different approaches to intravenous nutrition(TPN) on the pattern of weight gain in preterm infants weighing less than 1500 g admitted to the neonatal intensive care unit(NICU) of Hajar Hospital in Shahrekord

Protocol summary

Study aim

Determining and comparing the effect of two different approaches to intravenous nutrition on the pattern of weight gain in preterm newborns weighing less than 1500g admitted to the neonatal intensive care unit of Hajar hospital in Sharekord.

Design

A controlled clinical trial with parallel groups, randomized, on 60 infants. Random Number Generator software is used for randomization.

Settings and conduct

Eligible neonates admitted to Hajar hospital neonatal intensive care unit are randomly assigned to the control group (with complete onset of intravenous feeding (TPN)) and the intervention group (with gradual onset of TPN) and their growth parameters include weight, height and head circumference up to the end of TPN and in the fortieth week of gestation (fertilization) are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants weighing less than 1500g.
Criteria for not entering: Major congenital anomalies; Syndromic features; Severe congenital disease; Gestational age more than 37 weeks; Weight more than 1500 grams; Age more than 3 days.

Intervention groups

Control group: Amino acid is prescribed at the rate of 3.5 g / kg and lipid is prescribed at the rate of 3 g / kg daily from the first day. Intervention group: Amino acid starts at 1 g / kg on the first day, increases 1 g / kg daily to reach a maximum of 3.5 g / kg per day, and lipid starts at 0.5 g / kg per day and increases 1 g / kg daily to reach a maximum of 3.5 g / kg per day.

Main outcome variables

Status of growth indicators including weight, height and head circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210207050284N1**

Registration date: **2021-02-26, 1399/12/08**

Registration timing: **prospective**

Last update: **2021-02-26, 1399/12/08**

Update count: **0**

Registration date

2021-02-26, 1399/12/08

Registrant information

Name

Ali Maleki Boroujeni

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of two different approaches to intravenous nutrition(TPN) on the pattern of weight gain in preterm infants weighing less than 1500 g admitted to the neonatal intensive care unit(NICU) of Hajar Hospital in Shahrekord

Public title
The effect of intravenous nutrition on weight gain pattern in premature infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Premature neonate less than 1500 g
Exclusion criteria:
Congenital anomaly Syndromic features Age over three days Severe illness Gestational age more than 37 weeks Weight more than 1500 grams

Age
From **1 day** old to **3 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Random Number Generator software, a random list of numbers from one to sixty is created. The first thirty numbers belong to the control group and the next thirty numbers belong to the case group. According to the order of hospitalization, infants are numbered from one to sixty and are placed in the control or intervention group based on the number.

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 Shahrekord University of Medical Sciences

Street address

Kashani Street,Vice Chancellor for Research,
Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.SKUMS.REC.1399.097

Health conditions studied

1

Description of health condition studied

Premature newborn

ICD-10 code

P07.30

ICD-10 code description

Preterm newborn, unspecified weeks of gestation

Primary outcomes

1

Description

Weight

Timepoint

Daily and 40th weeks of gestational age

Method of measurement

Scales

2

Description

Height

Timepoint

Weekly and 40th weeks of gestational age

Method of measurement

Meters

3

Description

Head circumference

Timepoint

Weekly and 40th weeks of gestational age

Method of measurement

Meters

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Dextrose starts with infusion rate of 6 mg / kg / min on the first day of life and its dose is adjusted to provide random blood sugar between 60 and 120 mg / dL. Lipid (Smoflipid emulsion 20%, manufactured by Fresenius Kabi Austria GmbH, contains soybean oil, medium chain fatty acid, omega 6 rich fish oil, olive oil and fat-soluble vitamins) at a rate of 3 g / kg and amino acid (aminoven infant solution 10% production of Fresenius Kabi Austria GmbH containing amino acid) starts at the rate of 5.3 g / kg. Enteral feeding starts at the first opportunity from 10 to 20 ml / kg per day depending on the infant's tolerance and when intral feeding reaches 100 ml / kg per day, intravenous feeding is stopped.

Category

Treatment - Drugs

2

Description

Intervention group: Dextrose begins at an infusion rate of 6 mg / kg / min on the first day of life and is adjusted to randomly adjust blood sugar levels between 60 and 120 mg / dL. Amino acids (10% neonatal amino solution produced by Fresenius Kabi Austria GmbH containing amino acids) from 1 g / kg per day and lipids (20% Smoflipid emulsion, produced by Fresenius Kabi Austria GmbH, containing soybean oil, medium chain fatty acid, rich fish oil From omega-6, olive oil and fat-soluble vitamins) start at 0.5 g / kg / day and increase by 1 g / kg both daily to a maximum of 5.3 g / kg / day for amino acids. And reach 3 grams per kilogram per day for lipids. Enteral feeding starts at the first opportunity from 10 to 20 ml / kg per day depending on the infant's tolerance and when intral feeding reaches 100 ml / kg per day, intravenous feeding is stopped.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal intensive care unit of Hajar Hospital in Shahrekord

Full name of responsible person

Roya Choopani

Street address

Kashani Blvd., Headquarters of Shahrekord University of Medical Sciences

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

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vcrt@skums.ac.ir

Grant name

Grant code / Reference number

3314

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Roya Choopani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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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