Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of weight gaining of Very Low Birth Weight (VLBW) neonates who intake 10% and 12.5% dextrose serum in NICU wards of Ali Asghar and Akbar Abadi hospitals from May to December, 2020

Protocol summary

Study aim

Considering the importance of prematurity and weight gain in long-term health outcomes, lack of an agreement on parenteral nutrition diets for Very Low Birth Weight (VLBW) neonates, and role of glucose in nutrition, this study investigates the effect of increasing calories by adding glucose intake on weight gain in premature neonates.

Design

A parallel-group, blinded, phase 3 clinical trial design of 82 patients who were divided into intervention and control groups sequentially.

Settings and conduct

The clinical trial will be conducted on VLBW neonates in Neonatal Intensive Care Unit (NICU) of Ali Asghar, Akbar Abadi, and FiroozAbadi from May to December 2020. All the neonates will receive Total Parenteral Nutrition (TPN). While neonates in the intervention group will intake 12.5% DW, those in the control group will intake 10% DW. Birth weight and neonate's weight in the fifth, seventh, tenth, and fifteenth days after birth will be recorded by a specific scale. We consider the length of hospitalization and the date on which the neonate will be released. The daily calories intaken will be calculated based on TPN, serum volume (until neonate meet 150cc/kg), and breastfeed (if applies). The procedure will be continued until samples reach their birth weights, the duration that is used as the primary criterion for efficacy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: one-to-thirty-day neonates with birth weights lower than 1500g Exclusion criteria: Septic neonates, due to probable undesired interventions

Intervention groups

Neonates, who meet inclusion criteria, receive Total Parenteral Nutrition (TPN) and will intake 10% and 12.5% dextrose water (DW) serum. Then, we compare the weight gaining of neonates intaken 12.5% DW with those intaken 10% DW.

Main outcome variables

Birth weight; Days receiving TPN; Steroid before birth; Surfactant, Daily weight; Invasive ventilation duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047807N1**
Registration date: **2020-07-05, 1399/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-05, 1399/04/15**
Update count: **0**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Farnaz Firuzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of weight gaining of Very Low Birth Weight (VLBW) neonates who intake 10% and 12.5% dextrose serum in NICU wards of Ali Asghar and Akbar Abadi hospitals from May to December, 2020

Public title

Comparison of weight gaining of premature neonates intaking 10% and 12.5% dextrose serum

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Birth weights under 1500 gr

Exclusion criteria:

Septic neonates

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Before sample inclusion, parents are provided with a detailed description of the clinical trial and are informed about dextrose serum dose. Considering the fact that samples of the trial are neonates, they have no understanding of the dosage and hence are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Commitee of School of Medicine- Iran University of Medical Sciences

Street address

Hemat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.IUMS.FMD.REC.1398.201

Health conditions studied

1

Description of health condition studied

Weight gain in premature neonates with birth wight lower than 1500g

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weight of neonate

Timepoint

Fifth, seventh, tenth, and fifteenth days after birth

Method of measurement

Standard scale

Secondary outcomes

1

Description

Duration of reaching the birth weight

Timepoint

Daily

Method of measurement

Registry

Intervention groups

1

Description

24-hour infusion of 12.5% dextrose serum (produced by Iran Injectable and Pharmaceutical Products Company (IPPC)) which is started from 70cc/kg and gradually increase to 150cc/kg until fifth day after birth

Category

Treatment - Drugs

2

Description

24-hour infusion of 10% dextrose serum (produced by

Iran Injectable and Pharmaceutical Products Company (IPPC)) which is started from 70cc/kg and gradually increased to 150cc/kg until the fifth day after birth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Farnaz Firoozian

Street address

Dastgerdi

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2

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Farnaz Firoozian

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Molavi

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3

Recruitment center

Name of recruitment center

FiroozAbadi Hospital

Full name of responsible person

Farnaz Firoozian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Farnaz Firoozian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Farnaz Firoozian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

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