

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of a new combination of total parental Nutrition on the treatment process of newborns admitted to the ICU

Protocol summary

Study aim

Given the known side effects of TPN including sepsis, electrolyte abnormalities and cost, we prepared to compare the two ways of preparing TPN (The usual method of manual preparation in the ward by a nurse in compression with a clinical pharmacologist making it in sterile conditions). Identify the preferred method that is associated with the least side effects and is also useful in cost effectiveness theory and that we submit our review to other health centers in the country.

Design

The clinical trial study was a randomized, single-blind, control group. The study population is all neonates admitted to NICU ward of Kashan Shahid Beheshti Hospital who will undergo TPN. The sample size was 26 people in each group. All infants with TPN indication were randomly divided into 4 groups using 4 blocks. The two groups were matched for sex, gestational age, and birth weight.

Settings and conduct

First group consists of infants who, provide all the contents of the TPN as provided by the neonatal care nurse to the patient within the ward. The second group will be attached to the TPN as directed by the physician in a fully sterile package, directly to the infant without any nurse manipulation. The contents of both TPNs were similar, in the first group the TPN contents were injected separately but in the second group, the TPN contents were combined and infused into an infusion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All neonates admitted to the neonatal intensive care unit who have a scientific indication of TPN onset. Exclusion criteria: Parental dissatisfaction Sepsis Get worse Receive TPN in less than 5 days

Intervention groups

The intervention group receives a standard TPN compound prepared by the clinical pharmacologist in sterile conditions.

Main outcome variables

Mortality, Hospitalization, Neonatal weight gain, Sepsis, Thrombophlebitis, Skin necrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181028041485N2**

Registration date: **2020-02-05, 1398/11/16**

Registration timing: **retrospective**

Last update: **2020-02-05, 1398/11/16**

Update count: **0**

Registration date

2020-02-05, 1398/11/16

Registrant information

Name

Morteza Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 87 3366 4648

Email address

yousefi.m@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2018-09-22, 1397/06/31

Actual recruitment end date

2019-04-19, 1398/01/30

Trial completion date

2019-05-04, 1398/02/14

Scientific title

The effect of a new combination of total parental Nutrition on the treatment process of newborns admitted to the ICU

Public title

The effect of new Total Parental Nutrition formula on infants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All neonates admitted to the neonatal intensive care unit who have a indication of starting TPN.

Exclusion criteria:

Parental dissatisfaction Sepsis Getting worse Receive TPN in less than 5 days

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent from the parents of infants, all infants with TPN indication will be randomly divided into 4 groups using 4-sided blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, neonates who were originally participants were blinded The data analyzer also analyzes the data with groups A and B.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical

Sciences

Street address

Hekmat Street 56, Qutb Ravandi Boulevard

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1397.072

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

premature neonates nutrition

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

Number of days admitted

Timepoint

The end of the study

Method of measurement

Day

2**Description**

Neonate weight gain

Timepoint

Every two days

Method of measurement

Kilogram

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: They are infants with TPN indication, that the TPN order is sent to the hospital's Combined Drugs Center, which has a sterile chamber and a negative pressure ventilator as directed by the treating physician, and the TPN contents center is provided by the pharmacist in fully sterile conditions. They were packaged in full packages and transported to the neonatal care unit and connected directly to the infant without any manipulation.

Category

Treatment - Drugs

2

Description

Control group: They are infants who, according to the usual procedure, have all the contents of the TPN prepared and delivered to the patient by a neonatal nurse within the ward.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

MohammadReza Sharif

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Boulevard Ravandi Boulevard, Hekmat Street 56

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr HamidReza Banafsheh

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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr MohammadReza Sharif

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected data is shareable and has no limitations

When the data will become available and for how long

The access period will be available after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

There is no limitation

From where data/document is obtainable

Deputy of Research of Kashan University of Medical Sciences

What processes are involved for a request to access data/document

The data are visible after request from the deputy of research and after confirmation of the request within one month

Comments