

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Nutritional support with energy and nutrient-dense formula for children with congenital heart defects: A clinical trial

Protocol summary

Study aim

The results of nutritional support with energy and nutrient dense formula for children with congenital heart defects

Design

clinical trial; single arm; without control group; without blinding; non randomized; phase 2; 40 patients

Settings and conduct

Infants on regular infant formula will be switched completely to high energy-high protein formula. Infants on breast milk and infant milk formula (IMF) will be given high energy-high protein formula to replace the IMF; and undernourished Infants on breast milk only will be included (for top up by high energy-high protein formula) at the discretion of the clinician. The infants will be evaluated for growth parameters (weight, length, MUAC and head circumference) at recruitment, every 3 weeks until surgery, or until they have reached a WFA of $\geq -1SD$

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Infants diagnosed with medium/high risk congenital heart diseases - Undernutrition infants with WFA $\leq -2SD$ - Infants who are candidates for surgery (palliative surgery or total correction) - Infants aged under 9 months - Infants with gestational age ≥ 37 weeks
Exclusion criteria: - Infants with other medical problems affecting nutrition - Infants with cow's milk allergy or galactosaemia - Infants with low risk lesions - Infants who receive parenteral nutrition

Intervention groups

Single arm study; Intervention group 1: high energy-high protein formula

Main outcome variables

weight, height, weight for age Z score (WFA), weight for length z score (WFL), length for age z score (LFZ), Mid arm circumference (MUAC), head circumference (HC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191224045880N1**

Registration date: **2020-02-18, 1398/11/29**

Registration timing: **retrospective**

Last update: **2020-02-18, 1398/11/29**

Update count: **0**

Registration date

2020-02-18, 1398/11/29

Registrant information

Name

Ehsan Aghaei Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 9662

Email address

ehsanaghaei1358@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2019-05-22, 1398/03/01

Scientific title

Nutritional support with energy and nutrient-dense formula for children with congenital heart defects: A clinical trial

Public title

Nutritional support with energy and nutrient-dense formula for children with congenital heart defects: A clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

children with moderate/high risk cardiac defects who are candidates for surgical repair being undernourished (Weight For Age z-score $\leq$ - 2)

Exclusion criteria:

Infants known to have non-cardiac medical problems that could independently affect nutrient intake, such as gastrointestinal malformations, renal failure, liver disease, neurological sequelae genetic conditions associated with growth failure Infants with low risk cardiac defects presence of cow's milk allergy and galactosaemia history of operation within 4 weeks from the time of screening receiving parenteral nutrition

Age

To 9 months old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Actual sample size reached: 40

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Children's Medical Center, 62 Qarib St. , Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3543

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

congenital heart diseases

ICD-10 code

Q24.9

ICD-10 code description

Congenital malformation of heart, unspecified

2**Description of health condition studied**

malnutrition

ICD-10 code

E64

ICD-10 code description

Sequelae of malnutrition and other nutritional deficiencies

Primary outcomes**1****Description**

weight for age Z score

Timepoint

3,6,9,12 weeks after the administration of the high-energy- high protein formula

Method of measurement

scale

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

weight for length Z score

Timepoint

3,6,9,12 weeks after the administration of the high energy-high protein formula

Method of measurement

scale and meter

2**Description**

length for age Z score

Timepoint

3,6,9,12 weeks after the administration of the high energy-high protein formula

Method of measurement

meter

3

Description

head circumference

Timepoint

3,12 weeks after the administration of the high energy-high protein formula

Method of measurement

meter

4

Description

Mid-upper arm circumference

Timepoint

3,12 weeks after the administration of the high energy-high protein formula

Method of measurement

meter

Intervention groups

1

Description

Intervention group: In this study, infants on regular infant formula will be switched completely to energy- and nutrient-dense formula (100 kcal and 2.6 g protein per 100 ml; Infatrini®, Nutricia, Zoetermeer, the Netherlands). Infants who receive a combination of breast milk and regular infant formula will continue breast milk in addition to energy- and nutrient-dense formula to replace the regular formula. Infants who receive only breast milk will receive, at the discretion of the clinician, energy- and nutrient-dense formula. The dose of the administered energy- and nutrient-dense formula will initiate with 35 kcal/kg/day to reach 100 Kcal/kg/day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's medical center

Full name of responsible person

Ehsan Aghaei Moghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Danone Nutricia

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

NL

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Aghaei Moghadam

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable