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Investigating the effect of adequate energy and protein intake for children after cardiopulmonary bypass surgery

Submission date
27/05/2020

Recruitment status
No longer recruiting

Registration date
10/09/2020

Overall study status
Completed

Last Edited
14/09/2020

Condition category
Neonatal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Congenital heart disease is the name for a group of problems in the development of the structure of the heart, which can affect the normal way the heart works. The term "congenital" means the condition is present from birth. If left without treatment some congenital heart diseases can be fatal. Typically open heart surgery is required to treat these conditions. This type of surgery uses a cardiopulmonary bypass (also referred to as a heart-lung machine), which is a technique that temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and the oxygen content of the body.

Previously, the investigators of this study have determined how much protein and energy are required by congenital heart disease patients during their first 5 days after cardiopulmonary bypass surgery. This study aims to investigate whether providing an adequate amount of protein and energy can improve the clinical outcomes of these children. The investigators will test whether a new formula, that provides an adequate amount of protein and energy based on their previous calculations, is better than the standard treatment that patients would usually receive, by comparing how long patients stay in hospital and if these patients develop any new infections. It is hoped that this will provide evidence for improved management of nutrition, and therefore and improved recovery rate, of vulnerable children with congenital heart disease.

Who can participate?
Children, aged between 1 month and 1 year old, with a diagnosis of congenital heart disease with planned treatment with cardiopulmonary bypass surgery

What does the study involve?
Participants will be randomly allocated one of two groups. For 5 days following their surgery, they will either receive standard nutrition after their surgery or they will receive the new formula that provides an adequate amount of protein and energy.

What are the possible benefits and risks of participating?
The new formula of milk powder in this study is designed based on a previous study by the

investigators. In that study, the energy and protein requirements in babies during the early days after open-heart surgery were examined. The previous study found some beneficial results in babies who were fed with the new formula (such as growing faster), as compared to those fed with a traditional formula (not enough energy and protein intakes to meet requirements). No side effects were found in the new formula. In this study of a larger group of babies, no risks are anticipated. The benefits may include less infection, earlier discharge from the intensive care unit and to go home, and faster growth and recovery.

Where is the study run from?
Guangzhou Women and Children's Hospital (lead center), two other hospitals in China, and one hospital in Australia.

When is the study starting and how long is it expected to run for?
From May 2020 to December 2023

Who is funding the study?
Guangzhou Women and Children's Hospital (China)

Who is the main contact?
Prof Jia Li
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Early enteral nutrition of adequate energy and protein intakes to meet requirements in children after cardiopulmonary bypass: An international, multicenter, randomized, controlled trial

Study objectives
Adequate energy and protein intake (4 g/kg day pf protein and 60 kcal/kg/day of energy), via enteral route, in congenital heart disease patients after cardiopulmonary bypass surgery, improves clinical outcomes: reduced rates of Children's Intensive Care Unit (CICU) infections, duration of CICU stay, and need for mechanical ventilation; and improved survival and anthropometric growth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/08/2020, the ethics committee of Guangzhou Women and Children's Hospital (No 9, Jinsui Road, Tianhe District, Guangzhou 510001 China; gwcmc_scidept@gwcmc.org; +86 020-38367270), ref: 31801

Primary study design
Interventional

Study design
International, multicenter, randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Congenital heart disease

Interventions
Participants will be randomly allocated in a 1:1 ratio to either the control or intervention group using a block randomization method where participants will be stratified into 4 sets of blocks according to their STAT risk category.

In the Control Group, a standard formula (1.4 g/100 mL, 67 kcal/100 mL, Nutrilon 1, Nutricia, Nederland B. V.) will be used to provide energy according to the current practice in each center, the amount of protein intake is about 1 g/kg/day.

In the New Formula Group, bovine pure whey protein isolate (BiPro, Davisco Foods International, Inc., MN, USA) will be added to the standard formula to achieve protein intake of 4 g/kg/day and energy intake of 60 kcal/kg/day.

The formulas will be prepared every 3 hours to prevent bacterial growth and delivered by an infusion pump via a nasogastric tube. In both groups, enteral feeding of the formulas will be initiated at 1 mL/kg/h at 6 hours after cardiopulmonary bypass surgery and increased by 1 mL/kg every 6 hours, until reaching or getting close to the goal energy intakes by 30 hours after cardiopulmonary bypass surgery. In the following 4 days, the daily formulas were made according to study group allocation.

Intervention Type
Supplement

Primary outcome(s)
1. New infections acquired during the Cardiac Intensive Care Unit (CICU) stay and the duration of antibiotic treatment assessed using patient notes at the time of CICU discharge
2. The duration of CICU dependency assessed using patient notes at the time of CICU discharge

Key secondary outcome(s)
1. Mortality:
1.1. During the first 7 days in the CICU assessed using patient notes at the time of CICU discharge.
1.2. During the total stay in the CICU assessed using patient notes at the time of CICU discharge.
1.3. During the total stay in the hospital assessed using patient notes at the time of hospital discharge.
1.4. At 30 days after admission to the CICU and randomization assessed using investigator records at 30 days after surgery.
1.5. The rates of survival up to 90 days, regardless of ICU and hospital discharge status assessed using investigator records at 90 days after surgery.
1.6. The proportion of patients who were alive 8 days after CICU discharge assessed using investigator records at 8 days after CICU discharge.
2. The number of readmissions to CICU within 48 h assessed using investigator records at 48 h after CICU discharge
3. The time to final (live) weaning from mechanical ventilatory support assessed using investigator records at the time of weaning
4. The time to (live) discharge from the hospital assessed using investigator records at the time of hospital discharge
5. The need for cardiovascular support assessed using the duration of pharmacologic or mechanical hemodynamic support and Vasoactive-Inotropic Score (VIS) assessed using patient notes at the time of CICU discharge
6. The rate of organ dysfunction:
6.1. Renal dysfunction:
6.1.1. Acute kidney injury defined as at least a doubling of the serum creatinine level recorded on admission, measured through blood samples taken at baseline and every CICU day.
6.1.2. Proportion of patients requiring renal replacement therapy, and the duration of such therapy in the ICU, assessed using patient notes after CICU discharge.
6.2. Liver dysfunction indicated by alanine aminotransferase, aspartate aminotransferase, total bilirubin and albumin, measured through blood samples taken at every CICU day
6.3. Cardiac dysfunction indicated by NT-proBNP measured through blood samples taken at every CICU day
7. Complication rate assessed from the rate of hypoglycemia (glucose level <2.2 mmol per liter), and the rates of hyperglycemia and the doses of insulin given, measured using patient notes at the time of CICU discharge
8. Nutritional status measured using changes in prealbumin and CRP on blood samples taken at every CICU day, mid-upper-arm circumference and triceps skinfold measured using skinfold calipers at the time of CICU discharge, and the rates of feeding intolerance assessed using investigator records at the time of CICU discharge.

Completion date
31/12/2023

Eligibility

Key inclusion criteria

1. Diagnosis of congenital heart disease and planned cardiopulmonary bypass
2. Aged between 1 month and 1 year
3. Informed consent given by parent(s) or legal guardian
4. Gestational age at birth >36 weeks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Months

Upper age limit
1 Years

Sex
All

Key exclusion criteria
1. Any major congenital abnormality such as congenital diaphragmatic hernia or tracheoesophageal fistula
2. Acquired extra-cardiac disorder that could independently affect the primary endpoint such as meconium aspiration with a need for high-frequency ventilation, persistent renal failure requiring dialysis, chylothorax and gastrointestinal necrosis, or postoperative use of steroids in ICU

Date of first enrolment
01/01/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Australia

China

Study participating centre
Guangzhou Women and Children's Medical Center
No.9, Jinsui Road
Tianhe District
Guangzhou

China
510000

Study participating centre
The Royal Children’s Hospital
50 Flemington Street
Parkville 3052
Melbourne
Australia
3000

Study participating centre
Shanghai Children’s Medical Center
No.101, Tangqiaobeiyuan Road
Pudong District
Shanghai
China
200135

Study participating centre
Nanjing Children’s Hospital
No.72, Guangzhou Road
Gulou District
Nanjing
China
210000

Sponsor information

Organisation
Guangzhou Women and Children's Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Guangzhou Women and Children's Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date