Effect of short-term, high protein intake on whole-body protein synthesis and breakdown and stress response in infants after cardiac surgery

Published: 15-10-2009 Last updated: 06-05-2024

Primary: To measure the effect of a high protein diet on whole body protein synthesis and breakdown, as well as on net whole body protein balance and production of urea in children after cardiac surgerySecondary: To measure the effect of a high...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac and vascular disorders congenital
Study type	Interventional

Summary

ID

NL-OMON37986

Source ToetsingOnline

Brief title Pediatric post-cardiac surgery protein metabolism

Condition

- Cardiac and vascular disorders congenital
- Protein and amino acid metabolism disorders NEC

Synonym malnutrition, wasting

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Ministerie van OC&W,Nutricia

Intervention

Keyword: Cardiac surgery, Hypermetabolic stress response, Infants, Protein metabolism

Outcome measures

Primary outcome

protein turnover: Total body protein synthesis, -breakdown and -balance

Secondary outcome

Plasmaparameters stress response: Glucose, insulin, cortisol, CBG,

IL-1b-6-8-10, IP-10, MCP-1 en TNF- α

Study description

Background summary

In critical illness, hypermetabolic stress response markedly increases whole body protein breakdown with concomitant lesser increase of protein synthesis, resulting in negative nitrogen balance and loss of lean body mass. Clinically this contributes to a higher morbidity and mortality, more ventilator days and increased length of stay on an Intensive Care Unit. Stimulation of synthesis of whole body protein improves protein balance. In adults, maximum protein synthesis capacity is 1.5-1.7 g/kg/d. In chronically catabolic, stunted children protein balance is increased by a dietary protein intake of 5 g/kg/d. Data on optimal protein intake in critically ill children is lacking. Furthermore it has been suggested that several nutrients like glutamine, arginine, nucleotides and polyunsaturated fatty acids have beneficial effects on the stress response.

Study objective

Primary: To measure the effect of a high protein diet on whole body protein synthesis and -breakdown, as well as on net whole body protein balance and production of urea in children after cardiac surgery Secondary: To measure the effect of a high protein diet on the post-operative hypermetabolic stress response and also defining an evidence based recommendation for optimal daily protein intake in children in the direct post-operative phase after cardiac surgery.

Study design

24 children will be randomly allocated in two groups of 12 before their surgery. Both groups receive an isocaloric diet during 3 days by bottle feeding and/or nasogastric tube starting direct postoperatively with a protein load of 2 g/kg/day or 5 g/kg/day. On day 3 whole body protein synthesis and -breakdown rates are measured by infusion of stable isotopes and collection of blood- and breathsamples. Also determinants of post-operative stress response will be measured in the bloodsamples.

Intervention

Diet with high protein load (5 g/kg/day)

Study burden and risks

At 4 set times during the study period (T=0 and 3x around T=46 hours) blood samples will be taken from already exsisting lines. Breath samples will be taken at 5 moments (T=0, 27,5 and 3x around T=46 hours) via the nasopharyngeal tube. The burden and risks associated with all the interventions will be negligible for the patients

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

Infants Atrial/ventricular septum defect surgery Intensive Care admission

Exclusion criteria

pregnancy term < 37 weeks signs of infection diabetes mellitus, hypothyroidism, adrenogenital syndrome, panhypopituitarism

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2012
Enrollment:	24
Туре:	Actual

Ethics review

Approved WMO	
Date:	15-10-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	
Date:	12-06-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO **ID** NL28210.000.09

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Study results

Date completed:	01-04-2014
Actual enrolment:	28

Summary results

Trial is onging in other countries