To define the optimal glucose intake in critically ill children

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primary objective:-to define the optimal glucose intake by quantifying endogenous glucose production and fractional gluconeogenesis in critically ill children.secundary objectives:-determine glucose utilization in relation with exogenous glucose...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35471

Source
ToetsingOnline

Brief title
define optimal glucose intake critically ill children

Condition

- Other condition
- Congenital cardiac disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
nvt

Health condition

ernstig zieke kinderen met verschillende aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: critically ill children, glucose intake

Outcome measures

Primary outcome

-endogenous glucose production

-fractional gluconeogenesis

-glucose utilization

-whole body protein balance.

- fractional albumin synthesis rate.

Secondary outcome

indirect calorimetry:determination of total energy expenditure

urine samples for nitrogen excretion: protein utilization

anthropometry

Study description

Background summary

Hyperglycaemia is common in critically ill children. it has been associated with increased morbidity and mortality in several studies of critically ill children. Intensive insulin therapy reduces morbidity and mortality in critically ill adults. The overall hypothesis is that critically ill children will benefit as well from strict glucose control via insulin. it is becoming increasingly evident that establishment of normoglycaemia and not the insulin infusion perse, is responsible for the observed favourable results. a high intravenous glucose input might be deleterious as it can induce hyperglycaemia. No studies were performed in critically ill children to investigate the effect

of different regimens of glucose intake on endogenous glucose production and on blood glucose concentration.

Study objective

primary objective:
-to define the optimal glucose intake by quantifying endogenous glucose production and fractional gluconeogenesis in critically ill children.
secundary objectives:
-determine glucose utilization in relation with exogenous glucose intake and endogenous glucose production.
-relate endogenous glucose response with the hormonal and inflammatory response.
-to determine the effect of different glucose infusion regimens on whole body protein balance (synthesis - breakdown)
- to determine fractional albumin synthesis rate to get more insight in the contribution of hepatic proteinsynthesis to whole body protein synthesis.

Study design

randomized crossover study with 2 regimens of exogenous glucose administered in different groups of critically ill children on the PICU.

(protocol page 10 study design)

Intervention

One group will first get the lower amount of glucose infusion followed by the higher amount. The other group will first get the higher amount of glucose infusion followed by the lower amount.
They all will get 2 times 2 stable isotopes.

Study burden and risks

not specific more risks other then the normal risks on the PICU.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-critically ill patients after elective surgery (cardial, craniofacial of scoliosis surgery) admitted to the ICU
-critically ill patients with various medical diseases and > 1 organ failure admitted to the ICU.
- with arterial line
-inclusion 1 to 12 hours after admission
-cardiorespiratory stable
-only parental glucose after admission

Exclusion criteria

endocrine disorders, liver failure, chromosomal disorders,
insulin therapy
no arterial line of after removal arterial line
no informed consent
in case of patient after elective cardiac surgery: no extracorporal circulation during cardiac surgery

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-01-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-06-2010

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26665
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2007-006054-26-NL
CCMO	NL19433.078.08
OMON	NL-OMON26665