Insulin and protein in critically ill children.

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Objective: 1. To determine protein balance in septic, critically ill children at baseline and during a Hyperinsulinemic Euglycemic Clamp, while receiving standard or high protein intake based on age group; 2. To assess insulin sensitivity and...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29492

Bron
Nationaal Trial Register

Aandoening

Critically Ill septic Children admitted to the PICU

Ondersteuning

Primaire sponsor: ErasmusMC - Sophia Children's Hospital
Overige ondersteuning: Sophia Foundation Scientific Research (SSWO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

WHole body Protein Balance.

Toelichting onderzoek

Achtergrond van het onderzoek

It has been reported that tight glucose control with insulin in adult critically ill surgical patients has reduced mortality rates. However, there is no evidence that this approach may be beneficial in critically ill children. In theory, insulin has several potential beneficial effects. It has metabolic effects (glycemic control, improve protein balance and dyslipidemia) and non-metabolic effects (protect against oxidative stress, endothelial dysfunction and regulation of inflammation). Under physiological conditions, there is a close interrelationship between protein and energy (glucose and fat) metabolism. An increase in the energy supply will not promote nitrogen retention unless the amino acid supply is adequate, and conversely an increased amino acid supply will be useless if energy is limiting. Furthermore, protein requirements in critically ill children reach beyond the traditional areas of nitrogen balance and protein metabolism. Individual amino acids exert a functional impact during critical illness on which insulin might have a significant effect. The effect of tight glucose control with insulin on protein requirements, and on the regulation of substrate metabolism in critically ill septic children of all ages needs further study.

Objective:

1. To determine protein balance in septic, critically ill children at baseline and during a Hyperinsulinemic Euglycemic Clamp, while receiving standard or high protein intake based on age group;

2. To assess insulin sensitivity and response in critically ill septic children;

3. To assess the relationship between protein turnover and glucose and fat metabolism in critically ill septic children.

Study design:
A prospective, translational study.

Study population:
Critically ill septic children.

Intervention:
The study consists of a 2 day, 7-hour primed continuous intravenous tracer infusion studies of which the last three hours will be with a HEC. The protocol will consist of a tracer study ([1-13C]Leucine, [ring-2H5]Phenylalanine and [3,3 2H2]Tyrosine, [6,6 2H2]Glucose and [1,1,2,3,3 2H5]Glycerol) on two days in which they will receive parenteral nutrition with two

different amounts of protein intake (according to age) in a cross over fashion.

Main study parameters/endpoints:
The main study parameter of the study is the change in protein balance between baseline and insulin infusion.

Doel van het onderzoek

Objective:

1. To determine protein balance in septic, critically ill children at baseline and during a Hyperinsulinemic Euglycemic Clamp, while receiving standard or high protein intake based on age group;

2. To assess insulin sensitivity and response in critically ill septic children;

3. To assess the relationship between protein turnover and glucose and fat metabolism in critically ill septic children.

Onderzoeksopzet

2 day study which starts once the subject is hemodynamically stable in the PICU. It consists of 7 hr tracer infusions of which the last 4 hrs will be with insulin infusion.

Onderzoeksproduct en/of interventie

Standard vs High Amino acid intake by means of Total Parenteral Nutrition for 24 hrs in a cross-over design. On both study days a primed , continuous stable isotope tracer infusion will be provided for 7 hrs, of which the last three hours will be with insulin infusion by means of a Hyperinsulinemic euglycemic Clamp.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children admitted to the Pediatric Intensive Care Unit:

1. Diagnosis of SIRS, sepsis or septic shock, as determined by the criteria of the First International pediatric sepsis forum (Pediatric Critical Care Medicine 2005 vol 6 page 3-8);

2. Indwelling central venous access placed for clinical purpose;

3. Drawing line placed for clinical purpose;

4. Need for total parenteral nutritional support for at least 2 days.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with metabolic diseases i.e.: urea cycle disorders, cystinuria and insulin dependent diabetes mellitus;

2. Patients with hepatic or renal failure;

3. Enteral feeds providing more than 20% of total daily protein and energy intake based on age and weight;

4. Insulin therapy prior to the start of the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1943

Register	ID
NTR-old	NTR2060
Ander register	NL : 28671.000.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A