SIRM-study: Using stable isotopes for repeated measurements of glucose, lipid and protein metabolism within a limited time frame

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To determine whether glucose, lipid and protein metabolism can be accurately measured using stable isotopes in the same patient on two occasions in a 48 hour interval.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32194

Source
ToetsingOnline

Brief title
SIRM-study

Condition

- Other condition

Synonym
methodology, study design

Health condition

methodologische studie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Metabole fonds AMC

Intervention

Keyword: metabolism, repeated measurements, stable isotopes

Outcome measures

Primary outcome

Glucose, glycerol and valine enrichments to calculate glucose production,

glucose uptake, lipolysis and proteolysis respectively.

Secondary outcome

N.A.

Study description

Background summary

In 2001, a landmark study was published showing an improved outcome in morbidity and mortality of critically ill patients in the ICU treated with intensive insulin therapy to achieve euglycemia. The underlying mechanism for this improved survival has not been clarified yet: either normoglycemia itself or the metabolic effects of insulin may be responsible (Van den Berghe G, Wouters P, Weekers F et al. Intensive insulin therapy in the critically ill patients. N Engl J Med 2001; 345(19):1359-1367).

In an upcoming study that will be performed in the *Onze Lieve Vrouwziekenhuis* Aalst, Belgium (under supervision of Dr. F. Nobels and Dr. L. Foubert) in collaboration with the metabolic research group of the Academic Medical Center in Amsterdam (Prof. Dr. H.P. Sauerwein, Dr. M.J.M. Serlie), we will investigate this question, by studying glucose, lipid and protein metabolism in male Caucasian non-diabetic patients undergoing CABG surgery.

In the main study, patients will be randomized to group A or B:
A = low-dose insulin infusion combined with euglycemia starting intraoperatively and continuing until the first 12 hrs in the ICU
B = high-dose insulin infusion combined with euglycemia starting

intraoperatively and continuing until the first 12 hrs in the ICU
Glucose, lipid and protein metabolism will be measured using stable isotopes on two occasions: 24 hours before and 24 hours after surgery.

The study design assumes that glucose, lipid and protein metabolism can be measured twice in a 48 hour interval. In other words, it assumes that the stable isotopes used to measure metabolism on day 1 do not interfere with the measurements on day 3.

To verify whether this assumption is correct, we have designed a pilot study, which is described below.

Study objective

To determine whether glucose, lipid and protein metabolism can be accurately measured using stable isotopes in the same patient on two occasions in a 48 hour interval.

Study design

Non-randomized intervention study in which each volunteer serves as his own control.

Intervention

Each volunteer undergoes identical interventions on day 1 and 3:
- At T = 0h, a primed continuous infusion of all isotope tracers will be started.
- At T = 2h, an infusion of insulin (20mU/m2*min) and glucose 20% will be started to maintain a plasma glucose level of 5 mmol/liter (hyperinsulinemic euglycemic clamp). Blood samples will be drawn regularly to determine the plasma glucose level.
- At T = 4:30h, the insulin infusion will be increased to 60mU/m2*min.
- At T = 7h, all infusions will be stopped and subjects will be offered a carbohydrate-rich meal.

Study burden and risks

Burden: Total in-hospital presence of 18 hours.
Risks: Stable isotopes are not radioactive and act as the normal biological equivalent and are thereby harmless.
During a hyperinsulinemic euglycemic clamp it is theoretically possible to induce a hypoglycemia. However, this is very unlikely as blood glucose is checked every five minutes and the glucose infusion is adapted accordingly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy Caucasian males with a stable weight 3 months before the study.

Exclusion criteria

No medication, no family history of diabetes, no vigorous exercise.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Actrapid
Generic name:	insulin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	ID
EudraCT	EUCTR2007-006745-41-NL
CCMO	NL20127.018.07