IFIS-study: Intermittent Fasting and Insulin Sensitivity In Lean Healthy Male Subjects.

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Investigate effect of IF on insulin resistance and possible role acylcarinitin profiles and glycolipids

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30484

Source ToetsingOnline

Brief title IFIS-study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym diabetes/diabetes

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: clamp, fasting, insulin resistance, intramyocellular lipids

Outcome measures

Primary outcome

Impact of IF on insulin sensitivity, acylcarnitin profiles and glycolipids.

Secondary outcome

n.a.

Study description

Background summary

An important feature of fasting is a change in fuel utilization. Glucose oxidation will decrease and lipid and ketone body oxidation take over. Besides the fact that a substantial part of oxidized lipids have a hepatic origin, a substantial part of FFA lies waiting in peripheral tissues (skeletal muscle, IMLC) to be oxidized. Our early ancestors (50.000 * 10.000 B.C.) had no unlimited access to food as most people in Western countries have these days. Furthermore they had to hunt/gather to obtain food and periods of fasting and exercise were followed by periods of feeding and rest. In the last few hundred years, but most notably very recently, a tremendous change had occurred in feeding and exercise behaviour leading to the troublesome obesity and diabetic epidemic. Skeletal muscle of diabetic and obese subjects contains more lipid than their healthy, lean counterparts. This is correlated to insulin resistance. Surprisingly the IMLC content of well trained endurance athletes is equivalent with the diabetic and obese subjects although these subjects are very insulin sensitive. A possible explanation for this finding could be that the high turnover of lipid (and it*s metabolites) in athletes. Intermittent fasting (IF) for two weeks also improves insulin sensitivity although IMCL and expression of glucose transporter 4 do not change. This possibly indicates that very subtle changes are responsible for differences in insulin sensitivity. We hypothesize that insulin sensitivity increases after a period of intermittent fasting because of an increased turnover/change in IMLC: subtle changes in glycolipids and acylcarnitin profiles could be responsible. If proven effective, IF could be a very simple and cheap measure to prevent obesity or insulin resistance.

Study objective

Investigate effect of IF on insulin resistance and possible role acylcarinitin profiles and glycolipids

Study design

Volunteers will be included and undergo two hyperinsulinemic euglycemic clamps separated with two weeks in which volunteers will be fasting intermittent. During the clamps insulin sensitivity will be measured as well as other parameters of glucose metabolism in plasma and muscle.

Intervention

Intermittent Fasting for two weeks.

Study burden and risks

Stable isotopes are harmless. Muscle biopsies can cause hematoma: a minimal invasive biopsy and pressure bandage are used in order to minimalize this risk. Volunteers can however experience a bruising feeling.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- * Age 18 < 35 years
- * BMI 20-25 kg/m2
- * Stable weight three months prior to study inclusion
- * Normal oral glucose tolerance test (OGTT) using the ADA-criteria

Exclusion criteria

- * Any medication
- * DM II in first degree family members
- * Hypertriglyceridemia or any other lipid metabolism disorder
- * Intensive sports (> three times weekly)
- * any medical disorder of significant relevance
- * *breakfast-skipper*

Study design

Design

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

Recruitment

NL Recruitment status:

Pending

Start date (anticipated):	01-10-2006	
Enrollment:	8	
Туре:	Anticipated	

Medical products/devices used

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

Ethics review

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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
EudraCT
ССМО

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