Circadian rhythms of glucose metabolism, adipose gene expression and coagulation in type 2 diabetes

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To determine whether different circadian rhythms exist between patients with type 2 diabetes and controls in glucose responses, and whether this difference is best detected by either continuous glucose measurement or venous blood sampling. To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON35845

Source
ToetsingOnline

Brief title
RHYTHM

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
diabetes, metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Abbot Nutrition,bedrijf

Intervention

Keyword: Adipose, Circadian, Coagulation, Type 2 diabetes

Outcome measures

Primary outcome

Difference between patients and controls in circadian glucose excursions,

hemostasis, and gene expression profiles in adipose tissue.

Secondary outcome

n/a

Study description

Background summary

Type 2 diabetes is a major threat to human health, due to the numerous microvasvular and macrovascular complications. Previous studies suggest an altered circadian rhythm of glucose metabolism, leukocyte clock gene expression and hemostasis in patients with type 2 diabetes. However, glucose metabolism and hemostasis have never been compared between patients with type 2 diabetes and controls in a single design. Circadian clock gene expression in adipose tissue may anticipate circadian changes in food intake, and a disturbance in this circadian rhythm may be involved in the pathophysiology of type 2 diabetes. However, circadian gene expression in adipose tissue has never been evaluated in patients with type 2 diabetes.

Study objective

To determine whether different circadian rhythms exist between patients with type 2 diabetes and controls in glucose responses, and whether this difference is best detected by either continuous glucose measurement or venous blood sampling. To determine whether patients with type 2 diabetes show altered circadian gene expression profiles in adipose tissue.

Study design

Open-label intervention study

Intervention

Subjects will take isocaloric meal replacement by standard liquid meal replacement (Ensure, Abbott industries) divided into three identical meals at fixed timepoints.

Study burden and risks

Subjects will record daily food intake for three days followed by a three day intervention period. During the intervention periods subjects will take three identical isocaloric meals at fixed timepoints. Patients will wear an actigraph and a device for continuous glucose measurements. On the first day of each intervention period a fasting blood sample will be obtained. On the evening of the second day patients will be admitted to the clinical research unit for 24 hours, for circadian profiles of postprandial glucose excursions and hemostasis. Four subcutaneous adipose tissue biopsies will be performed to investigate circadian gene expression. The risks associated with the nutritional intervention, continous glucose measurement and venous blood sampling are negligible. Total blood volume sampled will not exceed 220 ml. Subcutaneous fat biopsies from the periumbilical region will be preceded by local anesthesia with lidocain, will only cause minor discomfort and have negligible risks of hemorrhage or infection.

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

Patients: Male, type 2 diabetes, Age 30-75 yr, BMI 25-40 kg/m2
Controls: Male, Age 30-75 yr , BMI <25 kg/m2

Exclusion criteria

Patients:
Use of any other anti-diabetic drug than metformin
Acute or chronic metabolic disease (other than type 2 diabetes) that will impair metabolism or digestion and absorption of food, including gastro-intestinal, hepatic or renal disease
Inability to give informed consent
Shift work in the month before intervention
Crossing several timezones in the month before intervention;Controls
Any acute or chronic metabolic disease that will impair metabolism or digestion and absorption of food, including gastro-intestinal, hepatic or renal disease
Inability to give informed consent
Shift work in the month before intervention
Crossing several timezones in the month before intervention

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:	Recruitment stopped
Start date (anticipated):	23-02-2012
Enrollment:	12
Type:	Actual

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
CCMO	NL36145.018.11