# Metabolic day-night rhythms in type 2 diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

# **Summary**

# ID

NL-OMON26231

Source NTR

**Brief title** RHYTHM

#### **Health condition**

type 2 diabetes

# **Sponsors and support**

Primary sponsor: P.H.L.T. Bisschop, MD PhD
Department of Endocrinology
Academic Medical Center, Amsterdam
the Netherlands
Source(s) of monetary or material Support: P.H.L.T. Bisschop, MD PhD
Department of Endocrinology
Academic Medical Center, Amsterdam
the Netherlands

## Intervention

## **Outcome measures**

#### **Primary outcome**

Difference between type 2 diabetes patients and healthy controls in circadian rhythm of postprandial glucose excursions, hemostatic parameters and gene expression in adipose tissue.

#### Secondary outcome

Difference between type 2 diabetes patients and healthy controls in circadian rhythms of insulin excursions, free fatty acid responses and oxidative stress.

# **Study description**

#### **Background summary**

N/A

#### Study objective

Type 2 diabetes is a major threat to human health. Previous studies suggest an altered circadian rhythm of glucose metabolism, leukocyte clock gene expression and hemostasis in patients with type 2 diabetes, but type 2 diabetes patients have never been compared to healthy controls.

We hypothesize that the circadian rhythms of glucose tolerance, coagulation and adipose tissue gene expression are altered in patients with type 2 diabetes compared to healthy controls.

### Study design

During three days: Continuous measurements of subcutaneous glucose levels, body temperature, physical activity.

During a 24-hr admission: Frequent plasma measurements of glucose, insulin, FFA. coagulatory factors, oxidative stress. Adipose tissue biopsies at four timepoints over 24 hr, Continous measurement of heart rate variability.

#### Intervention

Subjects will replace all oral food intake by three identical meals (Enrich Plus, Abbott industries) at fixed timepoints, during three days. Furthermore they will adhere to a fixed sleep wake schedule.

On the third day patients will be admitted for 24 hours for frequent plasma measurements, holter registration and adipose tissue biopsies.

# Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

Patients:

1. Male;

- 2. Type 2 diabetes;
- 3. Age 30-75 yr;
- 4. BMI 25-40 kg/m2.

Age matched controls:

1. Age 30-75 yr;

2. Male;

3. BMI <25 kg/m2.

# **Exclusion criteria**

Patients:

1. Use of any other anti-diabetic drug than metformin;

2. 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;

- 3. Inability to give informed consent;
- 4. Shift work in the month before intervention;
- 5. Crossing several timezones in the month before intervention.

Controls:

1. Any acute or chronic metabolic disease that will impair metabolism or digestion and absorption of food, including gastro-intestinal, hepatic or renal disease;

- 2. Inability to give informed consent;
- 3. Shift work in the month before intervention;
- 4. Crossing several timezones in the month before intervention.

# Study design

# Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

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Control:

N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2012
Enrollment:	12
Туре:	Actual

## **IPD** sharing statement

Plan to share IPD: No

# **Ethics review**

Positive opinion	
Date:	29-12-2011
Application type:	First submission

# **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

ID
NL3086
NTR3234
METC AMC : 2011_104
ISRCTN wordt niet meer aangevraagd.

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# **Study results**

## Summary results

https://doi.org/10.1007/s00125-019-4813-5