

Metabolic day-night rhythms in type 2 diabetes.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26231

Bron

NTR

Verkorte titel

RHYTHM

Aandoening

type 2 diabetes

Ondersteuning

Primaire sponsor: P.H.L.T. Bisschop, MD PhD

Department of Endocrinology
Academic Medical Center, Amsterdam
the Netherlands

Overige ondersteuning: P.H.L.T. Bisschop, MD PhD

Department of Endocrinology
Academic Medical Center, Amsterdam
the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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, Continuous measurement of heart rate variability.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Room F5-165

Department of Endocrinology and Metabolism

Academic Medical Center, Amsterdam
D.J. Stenvers
Amsterdam
The Netherlands
+31 (0)20 5663507

Wetenschappelijk

Room F5-165

Department of Endocrinology and Metabolism

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D.J. Stenvers
Amsterdam
The Netherlands
+31 (0)20 5663507

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2012
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	29-12-2011
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	NL3086
NTR-old	NTR3234
Ander register	METC AMC : 2011_104
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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