Metabolic effects of morning light in obesity and type 2 diabetes

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To determine the direct effects of morning light intensity on postprandial glucose and lipid metabolism and metabolic gene expression in adipose tissue in obese subjects with and without type 2 diabetes.

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

Summary

ID

NL-OMON38552

Source
ToetsingOnline

Brief title
SUNRISE 2

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: STW subsidie (On Time)

Intervention

Keyword: adipose tissue, glucose metabolism, light, lipid metabolism

Outcome measures

Primary outcome

Postprandial glucose excursions, and expression of metabolic genes in adipose tissue.

Secondary outcome

- postprandial insulin excursions
- postprandial free fatty acid (FFA) excursions
- postprandial triglyceride levels
- morning glucocorticoid increase
- morning salivary melatonin decrease
- resting energy expenditure (REE)
- measurements of autonomic balance:
- skin temperature decrease
- heart rate variability
- hunger and satiety ratings
- clock gene expression in leucocytes

Study description

Background summary

Type 2 diabetes is a major threat to human health. Interestingly, the incidence of obesity and type 2 diabetes correlates to the presence of artificial light. Light for the non-visual system is detected in the retina by specialised intrinsically photosensitive retinal ganglion cells (ipRGCs) that communicate

directly to various hypothalamic areas, and thereby modulate hormonal secretion and autonomic activity. Light has time dependent autonomic effects in humans, and administration of a light pulse to rats directly alters metabolic gene expression in the liver. In a previously performed pilot study (METC 2012-341) light intensity did not directly affect the postprandial glucose and insulin levels in healthy lean males. In this second pilot study, we aim to determine if light directly influences human glucose metabolism in subjects with prediabetes (impaired glucose tolerance) and in subjects with type II diabetes. We hypothesize that morning bright light exposure decreases postprandial glucose excursions.

Study objective

To determine the direct effects of morning light intensity on postprandial glucose and lipid metabolism and metabolic gene expression in adipose tissue in obese subjects with and without type 2 diabetes.

Study design

cross-over intervention study

Intervention

Subjects enter the facility in the evening. They will remain in normal room light (100-200 lux) for 4 hours. They receive a standard meal 2 hrs before bedtime. They sleep for 8 hrs in the dark (1 lux). From wake-up time, they will be subjected to either bright light (4000 lux) emitted by EnergyLights ((Philips Consumer Lifestyle B.V., Drachten) or dim light (10 lux). 1 hr after lights on subjects will consume a standard 600 kcal liquid meal (EnsurePlus, Abbott Industries, 16.7% proteins, 53,8% carbohydrates, 29,5% fat). Blood samples will be obtained at regular intervals until 5 h after the meal. Resting energy expenditure (REE) will be measured 3.5 h after breakfast, An adipose tissue biopsy will be obtained 4 h after the meal. Visual scale questionnaires will be rated to assess hunger and satiety.

Study burden and risks

Total study duration is three weeks. Participants will visit the Academic Medical Center five times: three short visits (<1hr) and two 16h admissions. At study entry, patients will undergo physical examination and one blood sample will be obtained. Participants will record sleep-wake times in a diary for five days. Prior to each admission they will wear an actiwatch to verify adherence to a stable sleep-wake rhythm. During each admission, participants will sleep for one night at 1 lux in the experimental room. They will remain undisturbed during this night. In the morning blood samples will be obtained from an indwelling canula in a peripheral arm vein. Total amount of blood obtained

during the study will be 210 ml (100 ml at each admission and 10 ml at study entry). Subcutaneous adipose tissue biopsies from the periumbilical region will cause minor discomfort and a subcutaneous hematoma that will resolve over time. Subcutaneous adipose tissue biopsies have negligible risks of infection or haemorrhage. Use of EnergyLights may cause minor temporal complaints such as headache or tired eyes. The 400 ml (600 kcal) Ensure Plus breakfast may for some people be above the average breakfast size. This may cause a transient sense of fullness.
Patients will receive a financial compensation of 200 euros and travel expenses.

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

Group 1 (n<=8):
- age 18-80 years
- male sex
- BMI >25 kg/m2
- habitual wake-up time between 6:00 and 9:00
- no DM2: fasting venous plasma glucose <6.1 mmol/l and HbA1c <6.5%;Group 2 (n<=8):
- age 18-80 years
- male sex
- BMI >25 kg/m2
- habitual wake-up time between 6:00 and 9:00
- type 2 diabetes: fasting venous plasma glucose >6.9 mmol/l or HbA1c > 6.5%

Exclusion criteria

- use of any other medication than metformin that interferers with glucose metabolism or neuronal synaptic transmission (corticosteroids, anti-depressants, anti-epileptic medication, other psychotropic drugs, anti malarials)
- gastro-intestinal or metabolic disease that will interfere with digestion or metabolism
- neuropsychiatric illness including severe depression
- epilepsy
- hypertension
- ophthalmological abnormalities (e.g. retinopathy)
- lactose intolerance
- soy allergy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2014
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	EnergyLight
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-12-2013
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	NL46085.018.13