# Metabolic effects of morning light

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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.

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

## Summary

### ID

NL-OMON39953

**Source**
ToetsingOnline

**Brief title**
SUNRISE

### 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 (OnTime);Agiko stipendium (ZonMW)

### 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

# 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 this pilot study, we aim to determine if light directly influences human glucose metabolism. 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.

## 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). 1,5 hr after lights on subjects will consume a standard 600 kcal liquid meal (EnsurePlus). Blood samples will be obtained at regular intervals until 240 min after the meal. Resting energy expenditure (REE) wille be performed 3.5 hrs after breakfast. An adipose tissue biopsy will be obtained 4 hrs after the meal.

## 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 14hr 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 fat 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

**Public**
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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 18-50 years
- male sex
- BMI 18-25
- fasting plasma glucose < 5.6 mmol/L
- habitual wake-up time between 7:00 and 9:00

## Exclusion criteria

- medication interfering 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
- 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): | 11-03-2013 |
| Enrollment: | 8 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | EnergyLight |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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|---|---|
| Date: | 11-01-2013 |
| Application type: | First submission |

| | |
|---|---|
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-05-2013 |
| Application type: | Amendment |
| 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 | NL42188.018.12 |