

# De rol van hypocretine in het aansturen van eetgedrag

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Abnormal food-related motivation and self-control accompanied by aberrant brain responses are related to deficient hypocretin levels in narcolepsy patients and not found in sleepy patients with normal hypocretin levels.

## Ethische beoordeling

Positief advies

## Status

Werving gestart

## Type aandoening

-

## Onderzoekstype

Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

## ID

NL-OMON27831

## Bron

Nationaal Trial Register

## Aandoening

narcolepsy with cataplexie, idiopathic hypersomnia, hypocretin, fMRI, food, motivation, self-control

## Ondersteuning

**Primaire sponsor:** Radboud UMC

**Overige ondersteuning:** NWO VIDI no. 016.116.371

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

- Function MRI images <br>
- Behavioural data<br>
- Questionnaires

# Toelichting onderzoek

## Doele van het onderzoek

Abnormal food-related motivation and self-control accompanied by aberrant brain responses are related to deficient hypocretin levels in narcolepsy patients and not found in sleepy patients with normal hypocretin levels.

## Onderzoeksopzet

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## Onderzoeksproduct en/of interventie

This is an observational study in which fMRI and behavioural tasks are used.

# Contactpersonen

## Publiek

Ruth Holst, van  
Kapittelweg 29  
Room 1.28  
Nijmegen 6525 EN  
The Netherlands  
024-3668293

## Wetenschappelijk

Ruth Holst, van  
Kapittelweg 29  
Room 1.28  
Nijmegen 6525 EN  
The Netherlands  
024-3668293

# Deelname eisen

## **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

- Age: 18-60 years old
- Right-handed
- BMI-range between 20-35.

Control group:

- No current sleep, neurological or psychiatric disorder
- Will be matched on age and BMI (range 20-35) with patient groups

Patient groups:

- Narcolepsy with cataplexy, or primary hypersomnia (either narcolepsy without cataplexy or idiopathic hypersomnia without long sleep time). All disorders should have been diagnosed according to the International Classification of Sleep Disorders – Second Edition (ICSD-2) criteria (American\_Academy\_of\_Sleep\_Medicine, 2005).
- All patients who take medication should be willing and able to withdraw from taking medication for 1 week.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- Diabetes Mellitus
- (History of) clinically significant hepatic, cardiac, renal, cerebro-vascular, endocrine, metabolic or pulmonary disease
- Uncontrolled hypertension, defined as diastolic blood pressure at rest > 90 mmHg or systolic blood pressure at rest > 160 mmHg
- (History of) clinically significant neurological or psychiatric disorders and current psychological treatment other than narcolepsy or idiopathic hypersomnia.
- Deafness, blindness, or sensory-motor handicaps
- History of taste or smell impairments
- Drug, alcohol or gamble addiction in the past 6 months

- Inadequate command of Dutch language
- Extreme restraint eating (i.e. score restraint eating  $\geq 3.60$  (females) or  $\geq 4.00$  (males) on the Dutch Eating Behaviour Questionnaire; see also section 6.3.4)
- Current, strict dieting (i.e. specific diet and/or in treatment with dietitian)
- Food allergy to one of the ingredients used in the food rewards
- Contra-indications for MRI:
  - o Metal objects or fragments in the body that cannot be taken out
  - o Active implants in the body
  - o Using medical plasters
  - o Epilepsy
  - o Previous head surgery
  - o Pregnancy
  - o Claustrophobia

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	07-01-2014
Aantal proefpersonen:	60

Type:

Verwachte startdatum

## Ethische beoordeling

Positief advies

Datum: 11-04-2014

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38653

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL4368
NTR-old	NTR4508
CCMO	NL45550.091.13
OMON	NL-OMON38653

## Resultaten