

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 kataplexie, 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

- Behavioural data

- Questionnaires

Toelichting onderzoek

Doel 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

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Wetenschappelijk

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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 ≥ 3.60 (females) or ≥ 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 dietician)
- 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