De rol van hypocretine in het aansturen van eetgedrag

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27831

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Radboud UMC
Source(s) of monetary or material Support: NWO VIDI no. 016.116.371

Intervention

Outcome measures

Primary outcome

- Function MRI images

- Behavioural data

- Questionnaires

Secondary outcome

Actual food intake

Study description

Study objective

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.

Study design

1

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion
Date: 11-04-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38653
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results