Unravelling the sleepy brain: A neuroimaging study in central hypersomnolence disorders

No registrations found.

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

Summary

ID

NL-OMON24942

Source
Nationaal Trial Register

Brief title
CHD-MRI

Health condition

Narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia

Sponsors and support

Primary sponsor: CIHR
Source(s) of monetary or material Support: CIHR

Intervention

Outcome measures

Primary outcome

Neural correlates on regional brain volumes (cortical thickness, surface area, subcortical volumes), white matter integrity (fractional anisotropy and mean, radial and axial diffusivity) and BOLD response in patients with narcolepsy type 1, narcolepsy type 2 and idiopathic

hypersomnia versus healthy well-rested controls and acutely sleep-deprived controls during resting-state, sleep and while performing a vigilance task and a rewarded-associative memory task.

Secondary outcome

Neurocognitive performance profiles during the SART (response time, number of omission and commission errors, total errors), reward-associative memory task (response time, number of correct and incorrect responses) and multidimensional attention task (response time, number of correct and incorrect responses), questionnaire results (PSQI, ESS, SIQ, HADS and KSS scores) and sleep habits in the week prior to MRI acquisition (duration).

Study description

Background summary

Central disorders of hypersomnolence are mainly characterised by excessive daytime sleepiness despite normal timing of nocturnal sleep. All disorders greatly impair daily functioning. Three subtypes of central disorders of hypersomnolence are being distinguished: narcolepsy type 1, narcolepsy type 2, and idiopathic hypersomnia. While narcolepsy type 1 originates from a selective loss of hypothalamic hypocretin-producing neurons, the pathophysiology underlying narcolepsy type 2 and idiopathic hypersomnia remains to be fully elucidated. It is probable that different causes may lead to these phenotypes.

The underlying brain circuit abnormalities of only narcolepsy type 1 have so far been identified using small sample groups, but their correspondence with other hypersomnolence disorders has yet to be investigated. As distinctive features between narcolepsy type 2 and idiopathic hypersomnia have not clearly been defined and given the clinical similarities between narcolepsy type 2 and idiopathic hypersomnia, the question arises whether the current third edition of the International Classification of Sleep Disorders (ICSD-3) classification addresses two separate entities or arbitrarily splits a heterogeneous group of patients. This is further emphasised by > 50% diagnosis crossover of NT2 and IH after repetition of diagnostic testing. In the future, the neural signatures of different central disorders of hypersomnolence could reveal transdiagnostic disease dimensions and help to improve classification of central disorders of hypersomnolence and potentially treatment options.

Study objective

We expect brain structure and functioning to be different in the hypothalamus, thalamus, brainstem, amygdala, medial prefrontal cortex, cingulate cortex, pre- and postcentral cortex, basal ganglia and visual cortex in patients as compared to controls. We also hypothesize narcolepsy type 2 and idiopathic hypersomnia to show similar brain structure and activation.

Study design

Study will start with one week of actigraphy and a sleep diary. After this week MRI acquisition will be performed. Healthy controls will undergo the protocol twice, once well-rested and once with a night of partial sleep deprivation in the night before MRI acquisition.

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

Patients:
• Definite narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia, diagnosed according to the International Classification for Sleep Disorders – Third Edition (ICSD-3) criteria;
• Age between 18 and 65 years old;
• Normal or corrected-to-normal vision;
• Informed consent.

Healthy controls:
• Age between 18 and 65 years old;
• Normal or corrected-to-normal vision;
• Informed consent.

Exclusion criteria

• Systemic or neurological diseases (e.g., infections, inflammatory disorders, dementia, epilepsy);
• Having worked on night shifts during the last month;
• < 18 or > 65 years of age;
• Major psychiatric disorder (e.g., major depression, psychotic or bipolar disorder);
• History of head injury, encephalopathy, former intracranial surgery, alcoholism or substance abuse;
• Contraindications for MRI exam (e.g., claustrophobia, metallic implants).

For patients:
• Previous REM sleep behaviour disorder, insomnia, obstructive sleep apnoea or restless legs syndrome diagnosis according to the medical records;
• REM sleep behaviour disorder or restless legs syndrome symptoms at least 1x/month as screened with the Single-Question Screening for REM Sleep Behaviour Disorder and Restless Legs Syndrome Screening Questionnaire.

For healthy controls:
• REM sleep behaviour disorder as screened by the Single-Question Screening for REM Sleep Behaviour Disorder;
• Restless legs syndrome as screened by the Restless Legs Syndrome Screening Questionnaire (score > 6);
• High-risk for obstructive sleep apnoea according to the Stop-Bang questionnaire (score > 4);
• Insomnia disorder by the Insomnia Severity Index (score > 14);
• Circadian rhythm disorder;
• Short sleepers (< 6 hours on average) or irregular sleep schedules.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2019
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion

Date:	01-08-2019
Application type:	First submission

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
NTR-new	NL7927
Other	METC VUmc / ToetsingOnline : 2019-001 / NL68388.029.18

Study results

Summary results
NA