Behavioral and psychological characteristics of children with narcolepsy

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With this study we aim to investigate the emotional development, behavior, social behavior, variation in personality traits and intellectual functioning in a group of children who are diagnosed with narcolepsy with of without cataplexie, according...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON40494

Source
ToetsingOnline

Brief title
Behavioral and psychological characteristics of children with narcolepsy

Condition

- Sleep disturbances (incl subtypes)

Synonym
Narcolepsy

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: VIDI subsidie nummer 0.16.116371 t.n.v. S. Overeem

Intervention

Keyword: Behavior, Children, Narcolepsy, Psychology

Outcome measures

Primary outcome

Given the exploratory nature of the study, there are several primary study parameters. Regarding the personality there is particular interest in the dimensions: 'extraversion' and 'emotional stability'. These are obtained from the Hierarchical personality questionnaire for children (HIPIC) and the Dimensional Personality Symptom Item Pool (DiPSI) and serve as the primary study parameter for personality traits. Social behavior is measured by the subscale 'autistic behaviors' obtained from the Social Emotional Questionnaire (SEV). The overall IQ score obtained from the Wechsler Intelligence Scale (WISC-III-NL) is chosen as the primary parameter for intellectual functioning.

Secondary outcome

Secondary outcome measures include 'internalizing' from the Child Behavior Checklist (CBCL) and the total score of the Child Depression Inventory (CDI).

Study description

Background summary

Narcolepsy is a chronic, neurological sleep disorder characterized by excessive daytime sleepiness (often manifested in uncontrollable sleep attacks), cataplexy, sleep paralysis, hypnagogic hallucinations and disturbed nocturnal sleep. In the late 90's it was clear that narcolepsy is caused by a deficiency or absence of a neuropeptide called hypocretin (or orexin), which is produced by localized neurons in the lateral hypothalamus. Although it was previously believed that narcolepsy in childhood was rare, it is now clear that the complaints are often manifest in childhood. It is generally assumed that

children with narcolepsy have a different behavioral and psychological profile compared to children without narcolepsy, however nuanced and longitudinal research on various aspects of the behavioral and psychological functioning and its development is lacking to date.

Study objective

With this study we aim to investigate the emotional development, behavior, social behavior, variation in personality traits and intellectual functioning in a group of children who are diagnosed with narcolepsy with of without cataplexie, according to the ICSD-2 criteria. The results will be compared with the results of a group of children with juvenile idiopathic arthritis and a healthy control group. By comparing the results of the narcolepsy group with the results of the juvenile ideopathic artritis group, we gain information about the specificity of the results. Are the results unique for narcolepsy, of do they appear to be related to the overall burden of chronic diseases? The variables will be monitored in time and the effect of the narcolepsy treatment on these variables is evaluated.

Study design

The study is exploratory. The design is longitudinal with a cross sectional analysis at T0. Both children who have a diagnoses of narcolepsy as children who receive a diagnoses of narcolepsy during the course of the study, will be followed. In total there will be 3-4 (depending on the time of diagnosis) measuring moments, in we use questionnaires as instruments. The children who receive a diagnoses of narcolepsy during the course (inclusion time 2 years), will also be tested on intelligence and some additional concentration tasks before the treatment of narcolepsy has started. These test will be repeated after one year.

Study burden and risks

The study requires effort of parent (s) / guardian (s) and the child itself. Parent (s) / guardian (s) and children receive a set of questionaires 3 to 4 times in a time span of 2 years. They are requested to complete the set of questionnaires and return these. The time investment per set of questionnaire for parents is approximately 110 minutes and for the child about 50 minutes. Children with a 'new diagnoses' of narcolepsy will be administered an intelligence test and some additional concentration tasks on two different times. This will take approximately 90 minutes each time. If desired, the results of this intelligence task can be shared whit the child and the paren (s)/ guardian (s).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Narcolepsy:
- Children with the diagnoses of narcolepsy according to the ICSD-2 criteria (both with and without cataplexy);- Due to age restrictions of the various instruments, children from 7 to 16 years old will be included in this study. For children who are diagnosed with narcolepsy during the course of the study and will participate as 'new diagnosis', an upper limit of 15 years has to be maintained. This is related to the age restriction of the WISC III NL;- Under treatment at one of the participating centers (ie Kempenhaeghe, UZ Gent, MC Haaglanden and LUMC);Juvenile idiopathic arthritis:;- Children with a diagnosis of juvenile idiopathic arthritis according to ILAR classification
- Children between the ages of 7 to 16 years
- At least one year under the supervision of a specialist

- Minimal treatment with NSAIDs and MTX;Healthy controls:;- Children between the ages of 7 to 16 years
- No medical diagnosis / treatment

Exclusion criteria

For both clinical groups and healthy controls:;- - Intellectual disability of the child (IQ <70)
- Intellectual disability of either parent (s) / guardian (s) (IQ <70)
- Problems with command of the Dutch language by the child
- Problems with command of the Dutch language by both parent (s) / guardian (s);Additional for healthy controls:
- A medical diagnosis requiring active treatment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2014
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2014

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL44822.058.13