# Behavioral and psychological characteristics of children with narcolepsy

Published: 12-03-2014 Last updated: 28-09-2024

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

1 - Behavioral and psychological characteristics of children with narcolepsy 25-05-2025

### 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

Public Epilepsiecentrum Kempenhaeghe

Sterkselseweg 65 Heeze 5591 VE NL **Scientific** Epilepsiecentrum Kempenhaeghe

Sterkselseweg 65 Heeze 5591 VE NL

# **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
Туре:	Actual

# **Ethics review**

Approved WMO Date:

12-03-2014

Application type: Review commission: First submission 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 CCMO **ID** NL44822.058.13