Long-term neuropsychological outcome in pediatric anti-NMDAR encephalitis

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Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42623

Source
ToetsingOnline

Brief title
Outcome in pediatric NMDARE

Condition

- Autoimmune disorders
- Encephalopathies
- Cognitive and attention disorders and disturbances

Synonym
hersenontsteking, NMDA receptor encefalitis

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Ministerie van OC&W,VENI

Intervention

Keyword: Encephalitis, Neuropsychological assessment, NMDAR, Outcome

Outcome measures

Primary outcome

Identification of clusters of impairment in cognition and behavior after

pediatric anti-NMDAR encephalitis

Secondary outcome

- Identification of risk factors affecting functional outcome

- Analyzing progression or remission over time

- Analyzing the phenomenom of 'growing into deficit'

Study description

Background summary

Anti-NMDAR encephalitis is a recently discovered new disease. Forty percent of patients are children, and it is the most common immune-mediated disease in children, beyond acute disseminated encephalomyelitis (ADEM) or acquired demyelinating syndromes (ADS). Anti-NMDAR encephalitis is a severe disease, and 75% of patients are admitted to the pediatric ICU. However, patients can recover well with adequate immunotherapy. Our large observational cohort study has shown that 85% of children recover *well*, although it can take up to 24 months. Despite good recovery, there is evidence that many patients are left with neuropsychological and behavioral impairments, but the exact extent is unknown. Formal neuropsychological assessment is only described in two international studies including nine adults and two children. These two small studies found impairments in memory, attention, behavior, and executive functioning.

Study objective

Our aims are to identify the clusters of impairments in cognition, behavior, quality of life, and fatigue in children after anti-NMDAR encephalitis, to identify risk factors affecting functional outcome and to assess the progression or remission over time. There will be special emphasis on the age

effect of *growing into deficit*.

Study design

A part of the study is cross-sectional (including children with anti-NDMAR encephalitis before Jan 2015), another part is prospective (children with anti-NMDAR encephalitis after Jan 2015)

Study burden and risks

Patients participating in the cross-sectional part of the study will be assessed once. The duration of the assessment interview will be two hours. Patients participating in the prospective part of the study will be assessed briefly during hospital visit to their treating physician at three months, and they will have a two hours assessment interview at 6, 12 and 24 months after onset of disease.

Assessment has negligible risks, although the identified issues can possibly lead to sadness.

Anti-NMDAR encephalitis is freqently seen in children (40% of the cases). The study goal can not be achieved analyzing adult patients, because the brain and immune system are different in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Cross-sectional part: patients who have had anti-NMDA receptor encephalitis before January 2015, who were age 18 or younger at disease onset and currently age 4 or older.
- Prospective parts: patients who have had anti-NMDA receptor encephalitis after January 2015, who were age 3.5 to 18 at disease onset
- Patient was diagnosed in Dutch tertiary pediatric hospitals, or antibody testing had been performed in our center.
- Patient speaks Dutch or English.

Exclusion criteria

- Age over 18 years at disease onset, or current age younger than 4
- Patient or legal representative is withholding informed consent
- Patient or legal representative objects after initial informed consent (see paragraph 8.4)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-04-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	13-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52688.078.15