Pathogenic Antibodies and (Rapidly Progressive) Dementia syndromes

Published: 20-03-2019
Last updated: 21-09-2024

1) Establish a comprehensive clinical and antibody profile of autoimmune synaptic encephalitis in dementia syndromes. 2) To assess outcome and provide diagnostic guidelines who to test and in whom testing will be unnecessary, and elucidate...

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

Summary

ID

NL-OMON47904

Source
ToetsingOnline

Brief title
PARADE study

Condition

- Autoimmune disorders
- Central nervous system infections and inflammations
- Psychiatric and behavioural symptoms NEC

Synonym
autoimmune encephalitis, inflamed brain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,NWO memorabel

Intervention

Keyword: antibodies, autoimmune, dementia, encephalitis

Outcome measures

Primary outcome

1) The characterization of (new) antibody-related dementia syndromes.

2) The frequency of the antibody-mediated dementia syndromes.

3) Outcome of autoimmune dementia.

Secondary outcome

1. What clinical and epidemiological markers are linked to the specific,

individual antibodies?

2. What markers define poor or good prognosis?

Study description

Background summary

Dementia syndromes are very common, their origin is often unclear, and there is no cure. Antibody-mediated encephalitis can mimic dementia syndromes as cognitive dysfunction can be prominent. Recently, there have been reports and small patient series with (rapid progressive) dementia and known antibodies, profiting from immunotherapy. However, late-onset autoimmune encephalitis can resemble less progressive dementia syndromes, easily missed and remain untreated. Literature does not provide clues of clinical markers suggestive for antibody-mediated dementia. The current studies are biased: selection of cases makes it difficult to relate to the average memory clinic patient; part of the patients are missed by using less sensitive and specific serum (instead of CSF), and by testing only for known antibodies. This work has led us to hypothesize that a small but significant part of patients with dementia syndromes have pathogenic antibodies that mediate the disease, especially in those patients with rapidly progressive dementia. Some antibodies are known, but others are to be identified.

Study objective

1) Establish a comprehensive clinical and antibody profile of autoimmune synaptic encephalitis in dementia syndromes.
2) To assess outcome and provide diagnostic guidelines who to test and in whom testing will be unnecessary, and elucidate biomarkers to predict who to test.
3) Determine the effects of patients* antibodies on synaptic function in vitro and in vivo with the goal of understanding how autoimmunity affects human behavior and memory.

Study design

observational cohort study

Study burden and risks

The study patients will have one venapunction with negligible risk and burden. As the diseases at hand can affect the patients cognition the study cannot be extrapolated in non-dementia patients.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients aged >= 18 years
- Patients who have given written informed consent
- patients with a clinical profile that fits one the described groups (rapidly progressive dementia of atypical dementia syndromes)

Exclusion criteria

- Age below 18 years
- Patient objects after initial informed consent
- Patient with mild cognitive impairment (MCI), subjective memory complaints or vascular dementia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2019
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2019
Application type:	First submission
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	NL58014.078.18