Identification of (bio)markers in Dementia with Lewy Bodies.

Published: 19-08-2015
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To identify novel diagnostic and prognostic (bio)markers of Dementia with Lewy Bodies.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON44099

Source
ToetsingOnline

Brief title
(Bio)markers in Dementia with Lewy Bodies.

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Dementia and amnestic conditions

Synonym
Dementia with Lewy Bodies, Lewy body dementia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw,Vriendenfonds;Stichting Parkinsonfonds

Intervention

Keyword: (Bio)markers, Dementia with Lewy Bodies, Diagnostics, Prognostics

Outcome measures

Primary outcome

The development of a study database and biobank for the identification of new diagnostic and prognostic (bio)markers of Dementia with Lewy Bodies.

Secondary outcome

To identify DNA and CSF proteome alterations in familial DLB that could be used as biomarkers of Dementia with Lewy Bodies.

Study description

Background summary

Dementia with Lewy Bodies is the second most common dementia in the elderly after Alzheimer*s Disease. Diagnosing Dementia with Lewy Bodies is difficult because of the highly variable symptoms of the disease and the considerable overlap of symptoms with Alzheimer's disease and Parkinson*s Disease. In addition, there is a lack of diagnostic as well as prognostic markers for Dementia with Lewy Bodies. A timely diagnosis will improve treatment and care for patients and their caregivers and will help in the selection of appropriate patients for clinical trials and the development of disease modifying treatment. Prognostic markers will further improve treatment and care of patients with Dementia with Lewy Bodies. This will lead to a higher quality of life and will reduce health care costs. Identifying novel clinical, imaging, blood and cerebrospinal fluid markers of Dementia with Lewy Bodies will highly contribute to these aims.

Study objective

To identify novel diagnostic and prognostic (bio)markers of Dementia with Lewy Bodies.

Study design

A multicenter prospective clinical cohort study which includes a

cross-sectional multicenter family substudy.

Study burden and risks

In this study patients will be examined once a year. Clinical data, brain MRI scans, blood and cerebrospinal fluid samples will be collected. In the family substudy, blood, cerebrospinal fluid samples and skin cells will be collected once. Regular clinical visits will be combined with data collection for this study. Therefore the burden of additional time is relatively low. There are no major risks associated with MRI-scanning, as no contrast enhancement is needed. The risk of a venapuncture is the occurrence of a hematoma. The risk associated with a lumbar puncture is low. A common complication is post-lumbar puncture headache, observed in 1-5% of patients. This risk is greatly reduced at higher age and with the use of a non-traumatic needle. Other complications such as meningitis and subdural spinal haematoma are very rare. Adverse events of skin biopsy may include minor bruising, local tenderness and a very low risk of infection. Participating in this study has no advantage for the specific individual. However, the relatively low burden of the individual could yield much information on the early phases of DLB. This is highly relevant to improve care of DLB patients in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with (prodromal) Dementia with Lewy Bodies or (prodromal) Parkinson's Disease Dementia (including patients without mild cognitive impairment).

Exclusion criteria

Mini Mental State Examination lower than 20 out of 30 points.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2015
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2015

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-01-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-01-2017
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	NL53037.078.15