Dementia with Lewy bOdies Project (DEvELOP): a longitudinal cohort study in DLB

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Dementia and amnestic conditions
Study type	Observational invasive

Summary

ID

NL-OMON45751

Source
ToetsingOnline

Brief title
DEvELOP

Condition

- Dementia and amnestic conditions

Synonym
Lewy body disease; Dementia with visual hallucinations and parkinsonism

Research involving
Human

Sponsors and support

Primary sponsor: VU Medisch Centrum
Source(s) of monetary or material Support: NWO (ZonMw),Stichting Dioraphte

Intervention

Keyword: biomarkers, concomitant Alzheimer pathology, dementia with Lewy bodies, longitudinal

Outcome measures

Primary outcome

To address the different research questions, the following study parameters

will be investigated:

- Clinical parameters (cross-sectional and longitudinal): physical/neurological

examination, neuropsychological test results; (caregiver) questionnaires

concerning neuropsychiatric, extrapyramidal and sleep symptoms, quality of life

and daily functioning.

- Biomarkers (cross-sectional and longitudinal): CSF proteins (Abeta42, Tau,

p-Tau); (patterns of) cerebral atrophy and vascular lesions on Magnetic

resonance imaging (MRI); visual rating and quantitative analysis of

Electroencephalography (EEG).

Secondary outcome

Not applicable

Study description

Background summary

Dementia with Lewy bodies (DLB) is the second most common form of dementia and clinically defined by cognitive impairment combined with visual hallucinations, parkinsonism and/or cognitieve fluctuations. However, it is a heterogeneous disease with varying symptomatology and disease course in individual patients. DLB is relatively understudied and especially longitudinal data are lacking. Pathologically, DLB is characterized by widespread distribution of Lewy bodies in the brain, although concomitant AD pathology (amyloid plaques and tangles)

is frequently found. The impact of concomitant AD pathology on clinical manifestation, disease course and biomarkers is unclear. The presence of AD co-pathology in DLB can be identified ante mortem by analysis of cerebrospinal fluid (CSF). Therefore, it is now possible to investigate the influence of concomitant AD pathology on the patient with DLB during life.

Study objective

The general objective of DEvELOP is to establish a prospective cohort of patients with DLB, to study the longitudinal course of clinical symptoms and biomarkers with a specific focus on concomitant AD pathology. Specific research questions that will be addressed include:
1. What is the effect of concomitant AD pathology on clinical phenotype and cognitive decline?
2. What is the effect of concomitant Alzheimer pathology on structural and functional changes in the brain?
3. Can AD pathology develop over time in DLB?
4. What is the effect of concomitant AD pathology on response to symptomatic treatment?

Study design

DEvELOP is a prospective cohort study. The duration of follow-up will be four years. The value of this cohort lies in the extensive phenotyping of the participants and the long duration of follow-up. This study is embedded in the Amsterdam Dementia Cohort, a prospective dementia cohort, that offers the same standardized multidisciplinary diagnostic work-up to every patient.

Study burden and risks

The risks associated with participation are negligible (risk of headache after lumbar puncture is reduced to 1-5% by use of atraumatic needle).The burden mainly consists of time investment, although the investigations at annual follow-up are mostly part of our current clinical care. Before inclusion, patients will have been screened at the VUmc Alzheimer center. When patients participate in DEvELOP, they will undergo additional neuropsychological tests and a series of questionnaires (estimated time of first visit: one hour for the patient and 30 mins for caregiver simultaneously). The investigations at annual follow-up are mostly part of our current clinical care (aprroximately 2 hours). Furthermore, additional neuropsychological tests and a series of questionnaires will be conducted as part of the DEveLOP study (estimated time 1 hour). The total time of the annual follow-ups is approximately 3 hours. At T=0.5 EEG will be repeated (estimated extra time: 2 hours) and at T=2 MRI and blood and CSF collection will be repeated (estimated extra time: 1.5 hours).

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

Signed informed consent projects P2005/160 (replaced by P2016/061), P2000/211, P2008/230 (will be replaced by P2017/315) .
Fulfilling criteria for possible or probable DLB or Mild cognitive impairment (MCI) with at least one core or suggestive DLB feature.
Clinical Dementia Rating <= 0.5 or 1, and/or MMSE > 18

Exclusion criteria

Severe physical or life-threatening conditions
Long-term previous use of antipsychotic drugs
No reliable caregiver present

Nursing home residency

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):	08-03-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	24-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27253
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55470.029.15
OMON	NL-OMON27253