# DEmEntia with Lewy bOdies Project (DEvELOP)

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | - |

## Summary

### ID

NL-OMON27253

**Source**
Nationaal Trial Register

**Brief title**
DEvELOP

**Health condition**

Dementia with Lewy bodies (DLB)

### Sponsors and support

**Primary sponsor:** VU Medical Center
**Source(s) of monetary or material Support:** ZonMW Memorabel, Alzheimer Nederland, Stichting Dioraphte

### Intervention

### Outcome measures

**Primary outcome**

Clinical parameters (cross-sectional and longitudinal)

• Cognitive functioning on neuropsychological testing

• DLB features

• Daily functioning

• AD pathology as assessed by AD proteins (Aâ42, t-tau and p-tau) in CSF.

• Brain atrophy on MRI

• EEG abnormalities

**Secondary outcome**

• Response to symptomatic therapy (cholinesterase inhibitors)

Biomarker parameters (cross-sectional and longitudinal)

# Study description

**Background summary**

Rationale: Dementia with Lewy bodies (DLB) is pathologically characterized by widespread distribution of Lewy bodies. Concomitant AD pathology is frequently found. In vivo, the presence of mixed pathology in DLB can be identified by the use of biomarkers in the cerebrospinal fluid (CSF). Little (longitudinal) research has been performed to study the influence of AD pathology on pathogenesis, clinical manifestations, biomarkers and treatment response in DLB.

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.

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.

Study population: We aim to include 100 patients with a diagnosis of probable DLB, possible DLB or mild cognitive impairment (MCI) with at least one suggestive DLB feature (McKeith criteria) from the memory clinic of the VUmc Alzheimer center. Patients will be divided in groups with (DLB-AD+) and without (DLB-AD-) co-existing AD pathology based AD-biomarkers in CSF.

Main study parameters/endpoints: Change in clinical parameters over time: neuropsychological test results; (caregiver) questionnaires concerning neuropsychiatric,

extrapyramidal and sleep symptoms, quality of life and daily functioning; physical examination. Change of biomarkers: proteins in blood and CSF; progression patterns and rates of cerebral atrophy and vascular lesions on Magnetic resonance imaging (MRI); visual rating and quantitative analysis of Electroencephalography (EEG).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks associated with participation are negligible. The burden mainly consists of time investment. Before inclusion, all patients have been screened at the VUmc Alzheimer center. When patients participate in DEveLOP, they will undergo additional neuropsychological tests and a series of questionnaires. Annual follow-up is mostly part of our regular clinical follow-up. At T=0.5 EEG will be repeated and at T=2 MRI and CSF collection will be repeated.

### Study objective

DLB patients with concomitant Alzheimer-type pathology (identified by CSF analysis) will have a more severe disease course (with a faster cognitive decline, more prominent structural and functional changes in the brain)

### Study design

baseline, 6 months, 1 year, 2 years, 3 years, 4 years

### Intervention

-

## Contacts

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## Eligibility criteria

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Signed informed consent

• Fulfilling criteria for possible or probable DLB (consensus criteria, (McKeith, 2005) or fulfilling criteria for MCI with at least one core or suggestive DLB feature

• Clinical Dementia Rating (CDR) = 0.5 or 1, and/or MMSE > 18)

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Severe physical or life-threating conditions

• Long-term previous use of antipsychotic drugs

• Nursing home residency

# Study design

## Design

**Intervention model:** Other
**Control:** N/A , unknown

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-03-2016 |
| Enrollment: | 100 |
| Type: | Anticipated |

# Ethics review

Positive opinion
Date: 24-05-2016
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 45751
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL5716 |
| NTR-old | NTR5869 |
| CCMO | NL55470.029.15 |
| OMON | NL-OMON45751 |

# Study results