DEmEntia with Lewy bOdies Project (DEvELOP)

Gepubliceerd: 24-05-2016 Laatst bijgewerkt: 15-05-2024

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)

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON27253

Bron
Nationaal Trial Register

Verkorte titel
DEvELOP

Aandoening

Dementia with Lewy bodies (DLB)

Ondersteuning

Primaire sponsor: VU Medical Center
Overige ondersteuning: ZonMW Memorabel, Alzheimer Nederland, Stichting Dioraphte

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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)

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

-

Contactpersonen

Publiek

A.W. Lemstra
Amsterdam
The Netherlands
020 – 444 0816

Wetenschappelijk

A.W. Lemstra
Amsterdam
The Netherlands
020 – 444 0816

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-03-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45751
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten