CHolinEsterase inhibitors to slow progression of Visual hALlucinations in Parkinson’s disease: a multi-center placebo-controlled trial(CHEVAL)

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Country

Netherlands

Title of project or programme

CHolinEsterase inhibitors to slow progression of Visual hALlucinations in Parkinson’s disease: a multi-center placebo-controlled trial(CHEVAL)

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ZonMw

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€ 514,337

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01/06/2013

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4.0

The project/programme is most relevant to:

Parkinson's disease & PD-related disorders

Keywords
Research Abstract

Visual hallucinations (VH) are the most common non-motor symptoms in Parkinson’s disease (PD). As an independent predictor for cognitive decline and nursing home placement they form an important disability milestone in the course of PD. According to current clinical guidelines minor VH do not require treatment per se. But as minor VH precede the stage of major VH without insight and PD associated psychosis (PDP) they offer an opportunity for early intervention. Neuroleptic drugs delay the transition into PDP but are unsuitable for early treatment of VH due to their side effects. We hypothesize that cholinesterase inhibitors (ChEI) are a well-tolerated alternative for the early treatment of minor VH to delay the progression to PDP.
Objective: investigate whether early treatment with ChEI delays the progression of minor VH to major VH without insight or PDP. In addition, we will measure motor control, psychotic symptoms, cognitive impairment, adverse events, quality of life, caregiver burden and care use. We assess the cost-effectiveness of early chronic treatment of VH with ChEI.

Study design: a randomized, double blind, placebo-controlled, multi-center trial with an economic evaluation.

Intervention: rivastigmine capsule 6 mg BID for 24 months or placebo BID for 24 months.

Outcome measures: the primary outcome is the proportion of patients that lose insight or convert to PDP. This endpoint is defined as (1) a score of 3 or 4 respectively on the UPDRS1-MDS thought disorder item or (2) the need to start treatment with atypical neuroleptic drugs. Secondary outcome measures are motor control (UPDRS III), psychotic symptoms (BPRS), cognitive impairment (MMSE), the number of adverse events, quality of life (PDQOL), caregiver burden (ZCBI), and care use. All relevant costs will be measured and valued.

Lay Summary
Further information available at:

Types:
Investments > €500k

Member States:
Netherlands

Diseases:
Parkinson's disease & PD-related disorders

Years:
2016

Database Categories:
N/A

Database Tags:
N/A