

A European multicentre double-blind placebo-controlled phase III trial of nilvadlpine in mild to moderate Alzheimer's disease

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Principal Investigators

Institution

Contact information of lead PI

Country

European Commission

Title of project or programme

A European multicentre double-blind placebo-controlled phase III trial of nilvadlpine in mild to moderate Alzheimer's disease

Source of funding information

European Commission FP7-Seventh Framework Programme

Total sum awarded (Euro)

€ 5,999,978

Start date of award

01/01/2012

Total duration of award in years

5.5

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Research Abstract

Alzheimer's disease (AD) is an ever-increasing public health concern among the aging population and is the most common form of dementia affecting more than 15 million individuals worldwide and around 5 million Europeans. The direct and indirect costs of AD and other dementias amount to more than €440,000 million each year (www.alz.org, 2010).

Even modest therapeutic advances that delay disease onset and progression could significantly reduce the global burden of the disease and the level of care required by patients. While there

are symptomatic-based drug therapies available for AD, these medications do not prevent the disease process itself. There is therefore an imperative to develop new treatments for AD that have disease modifying effects.

This double-blind placebo controlled study will test the efficacy and safety of nilvadipine in 500 subjects with mild to moderate AD over a treatment period of 18 months. There is a strong scientific rationale for this study: Nilvadipine, a licensed calcium channel enhancer, enhances A β clearance from brain and restores cortical perfusion in mouse models of AD. Nilvadipine is safe and well tolerated in AD patients and clinical studies with this medication have shown stabilization of cognitive decline and reduced incidence of AD, pointing to both symptomatic and disease modifying benefits. Male and female patients with mild to moderate AD aged between 50 and 90 with a range of medical morbidities and frailty will be included in the study. If this trial is successful, nilvadipine would represent an advance in the treatment of AD patients and would have a major impact on the health and social care costs incurred in Europe by this neurodegenerative disorder. Furthermore, the creation of the NILVAD network will support future clinical trials and research innovation in AD across Europe.

Lay Summary

Further information available at:

Types:

Investments > €500k

Member States:

European Commission

Diseases:

Alzheimer's disease & other dementias

Years:

2016

Database Categories:

N/A

Database Tags:

N/A