

NILVAD: A EUROPEAN PROJECT TO TEST THE EFFICACY OF A NEW DRUG FOR ALZHEIMER’S DISEASE



Alex Teligadas, Communications Officer, Alzheimer Europe

Alex Teligadas, Communications Officer, Alzheimer Europe, presents the recently launched NILVAD project. Supported with EUR six million within the European Commission’s Seventh Framework Programme, this project will conduct trials of the drug “nilvadipine” for the treatment of Alzheimer’s disease.

Nilvadipine has been in use for many years to treat hypertension. In 2007, researchers at Archer Pharmaceuticals found that the drug also blocks production of the amyloid protein that is believed to be central to the Alzheimer’s disease process. Nilvadipine reduced the development of amyloid plaques in the brain, cleared amyloid from the brain and increased blood flow to the brain. These results came from laboratory tests on mouse models and convinced scientists that a human trial would be worthwhile. This Phase 2 trial took place successfully in 2010 and led directly to the current NILVAD project.

Dr. Brian Lawlor, Project Coordinator, explains “People with Alzheimer’s disease and their carers will benefit greatly if this trial is successful as it would represent a significant advance in the area of Alzheimer’s disease treatments. NILVAD will also strengthen Alzheimer research networks in

Europe and help speed up developments to advance care for people with Alzheimer’s disease.”

NILVAD began on 1 January 2012 and is coordinated by Trinity College Dublin. The Phase 3 trial will perform a double-blind, placebo controlled study to test the efficacy and safety of nilvadipine in 500 subjects with mild to moderate Alzheimer’s disease over a treatment period of 18 months. Men and women aged between 50 and 90 in nine European countries will be included in the study. If the trial is successful, nilvadipine will be marketed for the treatment of Alzheimer’s disease in Europe.

The consortium consists of 17 partners based in ten EU member states and in the United States. The Project Coordinator is Dr. Brian Lawlor, Professor of Old Age Psychiatry at Trinity College Dublin. He will oversee the activities of more

NILVAD project partners

France	Centre Hospitalier Régional et Universitaire de Lille	Trinity College Dublin
Germany	GABO:mi Universität Ulm	University College Cork University College Dublin
Greece	Aristotelio Panepistimio Thessalonikis	Italy Mario Negri Institute
Hungary	Szegedi Tudományegyetem	Luxembourg Alzheimer Europe
Ireland	Molecular Medicine Ireland Newsweaver St. James’s Hospital	Netherlands Stichting Katholieke Universiteit
		Sweden Göteborgs Universitet
		UK King’s College London
		USA Archer Pharmaceuticals



First meeting of the NILVAD project team, February 2012, Dublin

than 40 team members working on the eight work packages (WP) that make up the project.

Three of these packages are directly involved in recruiting people for the trials, conducting the trials, collecting the results and analysing the final data:

WP4, directed by Prof William Molloy, will review the ethical and legal issues regarding recruitment of cognitively impaired adults. Prof Molloy's team will ensure that these issues are properly addressed in the project and will also establish an Ethics Advisory Board for the duration of the study.

WP5, led by Dr. Lawlor, is the platform that will conduct the clinical trials. This team will obtain ethical and regulatory approvals and will oversee the test sites. They will also examine any modifying effects of potential interventions such as frailty, nutritional status and social connection on treatment outcome.

WP6, headed by Prof Leslie Daly, will validate the trial design and procedures. The group will

also develop the statistical analysis plan, perform the final data analysis and produce the statistical section of the clinical study report.

The other work packages provide essential support such as project management, setting up the study framework, training and scientific direction. Alzheimer Europe is a partner in WP7, which will manage the dissemination and communication of information relating to the project. In addition, Maurice O'Connell, Board Member of Alzheimer Europe, sits on the NILVAD Scientific Board.

As of June 2012, the project framework, training programme and legal/ethical review are all in development. Authorisation requests to the national authorities and ethics committees have been submitted. These authorisations are needed for each country that will host a test site and must be approved before recruitment begins in October. A project website (www.nilvad.eu) and a secure intranet have been launched while the first project newsletter is planned for June.

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Dr. Brian Lawlor