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2019 Part the Cloud: Translational Research Funding for Alzheimer's Disease (PTC)

Placebo Controlled Multi-Ascending Dose Phase I Study in Healthy Volunteers

This Phase I clinical trial will test the safety of D3D, an experimental drug designed to slow harmful beta-amyloid protein accumulation during Alzheimer's disease.

PI

- Ph.D., University of Bayreuth, Germany, 1994
- Director at the Institute of Complex Systems: Structural Biochemistry, Forschungszentrum Jülich since 2005
- Member of the Board of Directors of the BMFZ, Heine University-Düsseldorf

STUDY

- CADRO category: Translational Research & Clinical Interventions
- This is Dr. Willbold's first Association award.

Background

One of the hallmarks of Alzheimer's disease is the accumulation of toxic beta-amyloid protein into plaques in the brain. Some therapies being developed for Alzheimer's broadly target beta-amyloid to try to prevent plaque formation.

Dr. Dieter Willbold and colleagues have been studying a synthetic, experimental drug that specifically targets one of the most harmful types of beta-amyloid. The drug, called D3D, attaches to small beta-amyloid protein fragments and prevents them from aggregating into harmful plaques. Dr. Willbold has studied this experimental drug in genetically engineered Alzheimer's-like mouse models. The researchers have found that this experimental drug in Alzheimer's-like mice led to significant improvement in cognition and a slowdown of brain damage. The researchers have already tested single doses of D3D in cognitively unimpaired adults as part of a phase I clinical trial to evaluate safety of this potential medication.

Research Plan

Building on their prior work, Dr. Willbold and colleagues will now perform the second portion of the phase I clinical trial, whereby they administer multiple doses of D3D to cognitively unimpaired adults. The researchers will start with low doses of D3D, and increase the dosage amount over the course of the study. This study will help Dr. Willbold more precisely understand how the experimental drug travels through the body (pharmacokinetics), and identify any safety concerns associated with higher doses.

Impact

This study is an essential first step to determine if this experimental drug D3D, is safe in humans. If successful, future clinical trials could then test the drug's efficacy in Alzheimer's. The study results could lead to further development of D3D as a potential therapy to delay or prevent beta-amyloid protein plaques from forming during Alzheimer's.