

＜シンポジウム 12—5＞神経疾患の臨床研究を目指したコンソーシアム

J-ADNI

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Background

In view of the upcoming clinical trials of disease-modifying drugs for Alzheimer's disease (AD), there is a compelling need for the establishment of surrogate biomarkers that reflect and predict the progression of AD, e.g., conversion from mild cognitive impairment (MCI) to AD. For this purpose, AD neuroimaging initiative (ADNI) is currently underway in US, collecting MRI and PET images as well as biological fluids, together with psychometric measures. In concert with this movement, we started Japanese ADNI (J-ADNI) sponsored by governmental funding bodies as well as domestic and international pharmas from April 2007.

Research plan

Thirty-eight clinical sites in Japan conduct a longitudinal study on 300 MCI individuals, 150 cognitive normal controls and 150 mild AD patients for 3 or 2 years using neuropsychological batteries, volumetric MRI, FDG-PET (currently ~67%) and amyloid imaging (~41%). We also collect biological fluids (blood, CSF ~38%, DNA samples). The protocols

are designed to achieve highest compatibility to US- and other ADNIs. Takeshi Iwatsubo serves as PI together with other core PIs (Clinical: Hiroyuki Arai and Takashi Asada, Neuropsychology: Morihiro Sugishita, MRI: Hiroshi Matsuda, PET: Kengo Ito and Michio Senda, amyloid PET: Kenji Ishii, Biomarker: Ryozo Kuwano).

Timeline and funding

A 5-year research program is being conducted. Public funding from NEDO (a foundation of ministry of economy, technology and industry) and ministry of health, labor and welfare comprise the 2/3, and funding from 11 pharmas, the 1/3, of the total budget amounting to ~500 million yen/year.

Progress

455 individuals (152 normal, 215 amnesic MCI, 88 AD) have been enrolled as of December 2010, and the analysis of baseline data on clinical and psychometric measures, MRI volumetry, FDG and amyloid PET, cerebrospinal fluids and apoE genotype are ongoing.