

Biomarkers for Alzheimer's disease can be trusted in clinical trials

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The best-established biomarkers for Alzheimer's disease have a low natural variation over two years. The results speak for the inclusion of these biomarkers in clinical trials of novel drugs against Alzheimer's disease.

The results are presented by researchers at the Sahlgrenska Academy at Göteborg University, Sweden, in the November 2007 issue of the *Journal of Alzheimer's Disease*.

"We show that the best-established diagnostic biomarkers for Alzheimer's disease stay at basically the same level during two years in patients with early Alzheimer's disease. This means that the biomarkers could be useful for detecting even minor biochemical changes induced by treatment in the clinical trials of novel drugs against Alzheimer's," says Henrik Zetterberg, Associate Professor at the Sahlgrenska Academy.

Dr Zetterberg and colleagues analyzed cerebrospinal fluid from more than 80 patients with mild cognitive impairment. Some of these patients developed full-blown Alzheimer's disease. The measured levels of the tau and amyloid-B proteins were compared in samples drawn from the same patients two years apart.

"If a novel drug candidate actually stops or slows down the neurodegenerative disease process in Alzheimer's disease, we should expect a normalized tau concentration in cerebrospinal fluid in patients

on active treatment. Such a change should be readily detectable also in a small and inexpensive pilot study, given the low intra-individual variation in biomarker levels over time that was detected in our study," Dr Zetterberg says.

Alzheimer's disease is an age-related brain-damaging disorder that results in progressive cognitive impairment and death. Three decades of progress have resulted in a profound understanding of the molecular mechanisms underlying the disease. In the past 10 years, this knowledge has translated into a range of targets for therapy, the most promising of which is amyloid-B.

Source: Swedish Research Council

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