

New blood test shows great promise in the diagnosis of Alzheimer's disease

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A new blood test demonstrated remarkable promise in discriminating between persons with and without Alzheimer's disease and in persons at known genetic risk may be able to detect the disease as early as 20 years

before the onset of cognitive impairment, according to a large international study published today in the *Journal of the American Medical Association (JAMA)* and simultaneously presented at the Alzheimer's Association International Conference.

For many years, the diagnosis of Alzheimer's has been based on the characterization of amyloid plaques and tau tangles in the brain, typically after a person dies. An inexpensive and widely available blood test for the presence of plaques and tangles would have a profound impact on Alzheimer's research and care. According to the new study, measurements of phospho-tau217 (p-tau217), one of the tau proteins found in tangles, could provide a relatively sensitive and accurate indicator of both plaques and tangles—corresponding to the diagnosis of Alzheimer's—in living people.

"The p-tau217 blood test has great promise in the diagnosis, early detection, and study of Alzheimer's," said Oskar Hansson, MD, Ph.D., Professor of Clinical Memory Research at Lund University, Sweden, who leads the Swedish BioFINDER Study and senior author on the study who spearheaded the international collaborative effort. "While more work is needed to optimize the assay and test it in other people before it becomes available in the clinic, the blood test might become especially useful to improve the recognition, diagnosis, and care of people in the primary care setting."

Researchers evaluated a new p-tau217 blood test in 1,402 cognitively impaired and unimpaired research participants from well-known studies in Arizona, Sweden, and Colombia. The study, which was coordinated from Lund University in Sweden, included 81 Arizona participants in Banner Sun Health Research Institute's Brain Donation program who had clinical assessments and provided blood samples in their last years of life and then had neuropathological assessments after they died; 699 participants in the Swedish BioFINDER Study who had clinical, brain

imaging, cerebrospinal fluid (CSF), and blood-based biomarker assessments; and 522 Colombian autosomal dominant Alzheimer's disease (ADAD)-causing mutation carriers and non-carriers from the world's largest ADAD cohort.

In the Arizona (Banner Sun Health Research Institute) Brain Donation Cohort, the plasma p-tau217 assay discriminated between Arizona Brain donors with and without the subsequent neuropathological diagnosis of "intermediate or high likelihood Alzheimer's" (i.e., characterized by plaques, as well as tangles that have at least spread to temporal lobe memory areas or beyond) with 89% accuracy; it distinguished between those with and without a diagnosis of "high likelihood Alzheimer's" with 98% accuracy; and higher ptau217 measurements were correlated with higher brain tangle counts only in those persons who also had amyloid plaques.

In the Swedish BioFINDER Study, the assay discriminated between persons with the clinical diagnoses of Alzheimer's and other neurodegenerative diseases with 96% accuracy, similar to tau PET scans and CSF biomarkers and better than several other blood tests and MRI measurements; and it distinguished between those with and without an abnormal tau PET scan with 93% accuracy.

In the Colombia Cohort, the assay began to distinguish between mutation carriers and non-carriers 20 years before their estimated age at the onset of mild cognitive impairment.

In each of these analyses, p-tau217 (a major component of Alzheimer's disease-related tau tangles) performed better than p-tau181 (another component of [tau tangles](#) and a blood test recently found to have promise in the diagnosis of Alzheimer's) and several other studied blood tests.

Other study leaders include Jeffrey Dage, Ph.D., from Eli Lilly and Company, who developed the p-tau217 assay, co-first authors Sebastian Palmqvist, MD, Ph.D., and Shorena Janelidz, Ph.D., from Lund University, and Eric Reiman, MD, Banner Alzheimer's Institute, who organized the analysis of Arizona and Colombian cohort data.

In the last two years, researchers have made great progress in the development of amyloid [blood](#) tests, providing valuable information about one of the two cardinal features of Alzheimer's. While more work is needed before the [test](#) is ready for use in the clinic, a p-tau217 [blood test](#) has the potential to provide information about both plaques and tangles, corresponding to the diagnosis of Alzheimer's. It has the potential to advance the disease's research and care in other important ways.

"Blood tests like p-tau217 have the potential to revolutionize Alzheimer's research, treatment and prevention trials, and clinical care," said Eric Reiman, MD, Executive Director of Banner Alzheimer's Institute in Phoenix and a senior author on the study. "While there's more work to do, I anticipate that their impact in both the research and clinical setting will become readily apparent within the next two years."

Alzheimer's is a debilitating and incurable disease that affects an estimated 5.8 million Americans age 65 and older. Without the discovery of successful prevention therapies, the number of U.S. cases is projected to reach nearly 14 million by 2050.

More information: Sebastian Palmqvist et al. Discriminative Accuracy of Plasma Phospho-tau217 for Alzheimer Disease vs Other Neurodegenerative Disorders, *JAMA* (2020). [DOI: 10.1001/jama.2020.12134](https://doi.org/10.1001/jama.2020.12134)

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