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Neurocognitive,
Biomarker, and
Health Outcomes
in Those at Risk for
Alzheimer’s Disease
Symptoms: ANCHOR-AD
Study Design

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OBJECTIVES

■ANCHOR-AD (NCT07142954) is designed to characterize clinical trajectories associated with baseline plasma P-tau217 in cognitively unimpaired individuals.

■This study may also inform which cognitively unimpaired individuals in the general population are likely to develop Alzheimer’s disease (AD) pathology.

CONCLUSIONS

■ANCHOR-AD will enable further research to support the growing body of AD epidemiology, particularly the natural progression of the early stages of AD, and the management of individuals who are cognitively unimpaired with elevated plasma P-tau217 levels.

■The biobank from this study will enhance future biomarker studies for AD and other neurodegenerative diseases.

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BACKGROUND

Biomarkers of AD:

■AD pathology can begin decades before individuals develop cognitive and functional symptoms.

■Biomarker evidence of AD pathology can be detected in cognitively unimpaired individuals.

■Phosphorylated tau at position 217 (P-tau217) is a blood biomarker that reliably detects AD pathology and is associated with faster cognitive decline and increased progression risk in cognitively unimpaired individuals.

Real-World Data:

■Prior studies have generated foundational knowledge on the natural history of cognitively unimpaired (preclinical) AD and the prognostic value of blood biomarkers by demonstrating significant associations between biomarkers and cognitive decline.

■A need exists to generate large-scale, longitudinal, real-world data integrating plasma P-tau217 with cognitive assessments across diverse populations.

■ANCHOR-AD is designed to address this gap by evaluating the prognostic utility of plasma P-tau217 and generating population-level data on cognitive trajectories and blood biomarkers in cognitively unimpaired individuals.

STUDY OBJECTIVES & ENDPOINTS

Primary:

■Determine rates of cognitive worsening within elevated and not elevated plasma P-tau217 cohorts (measured as change from baseline in the cognitive composite or any individual components).

Secondary:

■Compare rates of cognitive worsening between elevated and not elevated plasma P-tau217 cohorts (measured as change from baseline in the cognitive composite or any individual components).

■Characterize time to and rate of cognitive worsening within each cohort on different measures (ISLT, iDSSTm, CPAL, CFI, Xpresso).

■Develop a predictive model of progression to cognitive worsening based on participant characteristics.

■Establish the frequency of elevated plasma P-tau217 in cognitively unimpaired adults in the US and Japan.

Exploratory:

■Measure progression rate from not elevated to elevated plasma P-tau217 and develop a predictive model of biomarker change based on participant characteristics.

Community-Based Recruitment

Enrollment & Cohort Stratification

Building Blocks of ANCHOR-AD

■US: Single virtual site led by Care Access; recruitment via Care Access’s Future of Medicine Program (registry of potential participants) and Referral Program (referral pathway into clinical studies)

■Japan: Three clinical sites; recruitment through the University of Tokyo Hospital and Japan-Trial Ready Cohort – Japan National Registry

Elevated P-tau217:

Baseline P-tau217 ≥ cutoff determined using the Roche Elecsys assay

Stratified by age (55-64, 65-69, and 70-75 yrs) and geographic location

Not Elevated P-tau217:

Baseline P-tau217 < cutoff determined using the Roche Elecsys assay

Stratified by age (55-64, 65-69, and 70-75 yrs) and geographic location

Classified into intermediate and low sub-cohorts

Scale

~3,400 participants in US + Japan

Duration

7-year follow-up

Real-World Data Linkage

Optional EHR + health insurance claims broaden data (US)

Culturally Adapted Tests

Cognitive battery (ISLT, CPAL, CFI, iDSSTm, Xpresso); validated for US + Japan

Decentralized Design

Virtual assessments and local blood draws

Diversity

Community-based enrollment (US)
Three clinical sites (Japan)

Annual Plasma P-tau217

Roche Elecsys assay + additional biosample collection and biobank generation

Screening Period

Observational Period (7 Year Follow -Up)

Recruitment

Screening: Cognitively Unimpaired

Plasma P-tau217 testing

Elevated P-tau217 cohort

Not elevated P-tau217 cohort

Assessments at baseline

Assessments every 6 months
*The CFI and biomarker sample collection occur annually

Study end (7 years)

Screening: Cognitively Unimpaired

■N ≈ 15,000 individuals in the US

■N ≈ 9,000 individuals in Japan

Key Inclusion Criteria

• 55 – 75 years of age

• Self-report unimpaired cognition

• Adequate literacy, vision, and hearing for assessments at screening

• Access to internet or cellular service and a device compatible with assessments

Key Exclusion Criteria

• Seen a doctor about memory concerns

• History of cognitive impairment

• Received or receiving treatment for AD (e.g., investigational or amyloid-targeting therapy)

• Enrolled or participated in any AD-related study

Schedule of Assessments

Assessments and Activities	Baseline	Every 6 months	Every 12 months
Plasma P-tau217 Assay	X (screening visit)		X
Apolipoprotein E Genotype	X		
Biomarker Sample Collection	X		X
Self-Reported Comorbidities and Medication Use	X	X	
Cognitive Function Index	X		X
Continuous Paired Associate Learning Test	X	X	
Hospital Anxiety and Depression Scale	X	X	
International Daily Symbol Substitution Test-Medicines	X	X	
International Shopping List Test	X	X	
Montreal Cognitive Assessment Xpresso	X	X	
Quick Dementia Rating System	X	X	
Resource Use Inventory-Brief	X	X	

Anticipated Impacts

Establish natural history

Validate utility of P-tau217

Generate risk estimates

Inform clinical guidelines

Support early intervention trials

Bridge the US and Japan

Advance cognitive endpoint research

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Abbreviations:

AD = Alzheimer’s disease; CFI = Cognitive Function Index; CPAL = Continuous Paired Associate Learning Test; EHR = Electronic Health Records; iDSSTm = International Daily Symbol Substitution Test-Medicines; ISLT = International Shopping List Test; P-tau217 = phosphorylated tau at threonine 217; US = United States; Xpresso = Montreal Cognitive Assessment Xpresso

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