

Side effects and adverse events were more frequent in antipsychotic users vs non users ($p=0.0000$). Inappropriate use of antipsychotics according to the 2015 Beers Criteria was found in 9.3% out of the cases. **Conclusions:** Antipsychotics should be avoided for BPSD unless non-pharmacologic options have failed, or the patient is threatening self-harm or harm to others. In order to use these drugs appropriately, we should ask why the patient is taking the drug, whether it was appropriate initially, and whether it is still needed. A 25%-50% dose reduction is suggested every 1-2 weeks. Further details on this topic are strongly recommended.

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A PUBLIC RESOURCE OF BASELINE DATA FROM THE API AUTOSOMAL DOMINANT ALZHEIMER'S DISEASE COLOMBIA TRIAL



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Background: The Alzheimer's Prevention Initiative (API) was established to accelerate Alzheimer's disease (AD) prevention research, forge public-private partnerships, conduct prevention trials with maximal scientific benefit, clarify biomarker roles, and share data and biological samples after trials are completed. In conjunction with the Collaboration for Alzheimer's Prevention (CAP), API also agreed to share baseline data before its trials are completed. We now report availability of baseline data and brain images from the API Autosomal Dominant AD (ADAD) Colombia Trial, a prevention trial in *Presenilin 1* (*PSEN1*) E280A mutation carriers and non-carriers from the world's largest ADAD kindred. **Methods:** The API ADAD Colombia Trial is a 60-month randomized, placebo-controlled prevention trial of the investigational amyloid- β ($A\beta$) antibody therapy crenezumab in 252 unimpaired 30-60 year-old kindred members, including mutation carriers who were randomized to active treatment or placebo and non-carriers who receive placebo. The mutation is virtually certain to cause mild cognitive impairment (MCI) and dementia due to AD at respective the ages of 44 ± 5 and 49 ± 5 . For ethical reasons, participants have not received their mutation test results. Flortetapir ($A\beta$) PET, fluorodeoxyglucose PET, and MRI scans—and CSF and blood samples in those who consent—are acquired at baseline and several follow-up visits. GTP1 (tau) PET scans are proposed at ~months 30 and 60. The baseline data-sharing plan was developed to benefit the field while protecting participant identification and trial integrity. Several data attributes and information about how to request data will be available through the Global Alzheimer's Association Interactive Network (GAAIN). Subject-level data and images will be then shared with approved users. Other data and available biological samples will be shared after the trial is completed. **Results:** We will summarize participant characteristics, our available data and data-sharing plan, and how researchers can request and receive data. **Conclusions:** The API ADAD Colombia

Trial baseline data sharing program is intended to advance the study of preclinical AD, underscore the importance of data sharing in all trials, and do so in a way that protects participant identification and trial integrity.

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LANABECESTAT: SCREENING PERFORMANCE FROM THE AMARANTH STUDY



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Background: Lanabecestat inhibits beta-site amyloid ($A\beta$) precursor protein-cleaving enzyme 1 (BACE1) and reduces $A\beta$ production. Lanabecestat is under investigation as potential disease-modifying treatment for Early Alzheimer's Disease (defined as MCI due to AD or mild AD dementia). Here we summarize screening data and reasons for screen failure from the completed recruitment of the ongoing Phase 2/3 AMARANTH study (NCT02245737). **Methods:** Participants consented but not randomized were counted as screen failures. Participants could screen more than once depending on reason of initial failure. Screen failures were categorized as "entry criteria not met", "adverse event", "death", "subject decision", "caregiver decision" or "other". "Entry criteria not met" was further categorized by all applicable inclusion or exclusion criteria. Participants could fail more than one criterion (but not all participants were tested on all criteria). General order of screening assessments was not fixed by the protocol other than for key cognitive tests; in order, MMSE, RBANS and CDR. The study was conducted at 257 sites in 15 countries with enrollment occurring over a 3-year period. **Results:** 6871 Participants were screened to randomize 2218; 4653 (68%) were screen failures. A total of 5244 reasons were captured for screen failure due to rescreening and participants meeting more than one criterion. The most common reasons for screen failure were failure to meet RBANS delayed memory index criterion of at least 1 SD below normal (27%), lack of amyloid positivity by PET scan or CSF testing (23%), and failure to meet MMSE criterion 20-30 (16%). Other major causes of screen failures were "other", MRI findings, QTcF >470 ms, and lack of stable medication, each accounting for 2-3%. The remaining 19% of reasons for screen failures were comprised of individual entry criteria, adverse events, caregiver decisions or death, none of which exceeded 2%. **Conclusions:** The screen failure rate for the AMARANTH study was 68%. The primary reason for screen failure was an insufficient protocol-defined episodic memory deficit. Strategies to minimize screen failure rates in AD trials will continue to be a focus across the industry to minimize trial costs, timelines, and patient burden.

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INVESTIGATIONAL NEW ALZHEIMER'S DRUG TRICAPRILIN: POSSIBLE EFFECTS OF APOE ϵ 4 NON-CARRIER SELECTION AND SITE EFFECTS ON STUDY OUTCOMES IN A PHASE 2/3 STUDY IN MILD-TO-MODERATE ALZHEIMER'S DISEASE PATIENTS



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