

THE AFRICAN AMERICAN HEART STUDY

PARTNER FOR SUCCESS WITH THE ASSOCIATION OF BLACK CARDIOLOGISTS AS STUDY SITES AND PARTICIPANTS.

You Can Make a Difference!

The observational African American Heart Study will investigate the association between lipoprotein(a) and atherosclerotic cardiovascular disease in 5,000 African American participants in the U.S.

GLOBAL PRINCIPAL INVESTIGATOR:

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Sponsor: Amgen

HEART STUDY'S GOAL: Better Understand and Serve the Underrepresented

The African American Heart Study aims to provide insights into the association between lipoprotein(a) [Lp(a)] and atherosclerotic cardiovascular disease (ASCVD) risk in African Americans, a population historically underrepresented in research.



STUDY RATIONALE

High Lp(a) levels are associated with incident ASCVD, but research has primarily been conducted on individuals of European descent. Information on the association between Lp(a) levels with incident ASCVD in persons of African descent is lacking. Lp(a) levels differ by

race/ethnicity and are highly heritable, largely genetically determined, and unaffected by health behaviors. The African American Heart Study consists of self-identified African American, Black, or African-descent participants with ASCVD at enrollment (cases) and self-identified African American, Black, or African-descent participants without ASCVD at enrollment (controls) from cardiology and primary care practices. Real-world data (RWD) will be used to retrospectively characterize and prospectively follow cases and controls for at least 3 years. The primary objectives are to estimate the association between Lp(a) molar concentration and the presence of ASCVD at enrollment, to characterize sequence variants associated with Lp(a) molar concentrations, and to characterize sequence variants associated with the presence of ASCVD at enrollment. The key secondary objective is to estimate associations between Lp(a) molar concentration, sequence variants, and clinical factors with cardiovascular events during at least three years of RWD follow-up, separately among participants with and without ASCVD at enrollment. The other (non-key) secondary objectives are to describe comorbidity and medication burden among individuals with and without ASCVD at enrollment.



ABC MISSION

To Promote the Prevention and Treatment of Cardiovascular Disease, including Stroke, in Blacks and other Minorities and to Achieve Health Equity for all through the Elimination of Disparities.



OVERALL DESIGN

This study will enroll approximately 2,500 self-identified African American cases with ASCVD at enrollment and 2,500 self-identified African American controls without ASCVD at enrollment from cardiology and primary care practices across the US. The Health 360x™ platform will be used to screen practice electronic health records (EHR) and identify eligible cases and controls. Health 360x is a chronic disease and population health management platform. Patients report their health data to the platform (i.e., blood glucose, blood pressure, cholesterol, and weight). Doctors and coaches connected to the patients have an opportunity to review and interact with patients on Lp(a) data returned from the study. Health 360x also has integrations with 1upHealth to pull EHR data from health systems across the country. Health 360x integrates into the CRIO clinical trial management system. Once patients are identified, have provided consent, and populated in CRIO, Health 360x will support the aggregation of their EHR data and review of results (inclusion criteria for study). In addition, Health 360x will support downstream data aggregation and submission to deCODE, a subsidiary of Amgen with extensive expertise in genetic analyses. An enrollment visit includes a physical examination, weight, height, waist circumference, blood pressure measurements, completion of a questionnaire, and blood samples. Retrospective EHR and claims data will be used to characterize participants at enrollment. Prospective follow-up will be solely through events identified via linked EHR, claims data, and death records.

KEY INCLUSION CRITERIA

- ♥ Self-reported race as Black, African American, or of African descent
- ♥ 18-85 years of age at enrollment
- ♥ Matched 1:1 ASCVD case to control on age (+/- 3 years at enrollment), sex, and recruitment site
 - ASCVD cases require the presence of ASCVD, defined as a diagnosis or procedure code indicating a history of Myocardial Infarction (MI), coronary or lower extremity arterial revascularization, or significant coronary artery disease without prior revascularization at or prior to enrollment
 - Controls are participants free of ASCVD codes at or prior to enrollment



If you are interested in participating as a clinical site, please complete an interest form here:

<https://bit.ly/ABCHeartStudyInterestForm>.

Please access key publications, articles, and other relevant information:

- ♥ American Heart Association. African Americans and Heart Disease, Stroke. Available at: <https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease/african-americans-and-heart-disease-stroke>.
- ♥ CDC. Lipoprotein (a). Available at: [https://www.cdc.gov/genomics/disease/lipoprotein_a.htm#:~:text=High%20levels%20of%20lipoprotein%20\(a,made%20of%20protein%20and%20fat](https://www.cdc.gov/genomics/disease/lipoprotein_a.htm#:~:text=High%20levels%20of%20lipoprotein%20(a,made%20of%20protein%20and%20fat)
- ♥ Kronenberg F, et al. Eur Heart J. 2022; 43:3935-3946.
- ♥ Reyes-Soffer G, et al. Arterioscler Thromb Vasc Biol. 2022;42:e48-e60.
- ♥ Tsimikas S, et al. J Am Coll Cardiol. 2017;69:692-711.
- ♥ Tsimikas S, et al. J Am Coll Cardiol. 2018;71:177-192.
- ♥ Tsimikas S, et al. J Am Coll Cardiol. 2022;80:934-946.
- ♥ Virani, SS, et al. Prog Cardiovasc Dis. 2022;73:32-40.
- ♥ Wilson DP, et al. J. Clin Lipidol. 2019;13:374-92.

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