Researchers aim to see if patients are helped by genetic tests

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Researchers at the Stanford University Medical Center are conducting a clinical trial to determine whether giving patients genetic information about their risk of coronary artery disease will help motivate them to reduce that risk by changing their behavior.

Stanford Hospital & Clinics physicians will tell some of the patients recruited for the randomized trial whether they have any genetic markers for coronary artery disease, the leading cause of death in the United States. The researchers want to see whether these patients, armed with their genetic information, make positive changes to their lifestyle and eating habits, as well as adhere more faithfully to their prescribed drug regimens, compared with members of a control group.

“There’s a huge need to test this hypothesis,” said Joshua Knowles, MD, PhD, the lead investigator of the study and an instructor in cardiovascular medicine at the Stanford School of Medicine.

This is partly because the American Heart Association has concluded that, given the absence of data on how genetic testing actually affects patient outcomes, there is not enough information to advocate for such testing, Knowles said. And, at least for the moment, genetic tests are no better at predicting someone’s risk of coronary disease than old-fashioned diagnostic methods, such as looking at family history and measuring such factors as age, weight, blood pressure, cholesterol levels and diabetes status, he added.

Coronary artery disease results from the accumulation of fat, cholesterol and other substances along walls of the coronary arteries, causing them to harden and narrow and increasing the likelihood of a heart attack. Roughly half a million people die because of the disease each year in the United States.

Researchers overseeing the clinical trial, which is set to last about a year, are interested in recruiting roughly 100 adult patients who are at medium to high risk for coronary disease. All patients who enroll in the trial will undergo testing for dozens of genetic markers unequivocally associated with increased susceptibility to the disease. However, only half of the participants, selected at random, will be given the results of their tests. (At the end of the trial, all participants will be given their genetic-test results.)

Participants will be expected to make three visits to Stanford Hospital during the trial. They will have their medical history evaluated and undergo a physical exam. They also will receive standard care, including laboratory tests for lipids and a calculation of their risk of the disease based on traditional prediction models. Therapy will be based on current clinical guidelines and may include recommendations related to diet, exercise and lifestyle, as well as prescribed medication.

The researchers will gauge whether patients who received genetic-test results experienced improved outcomes by looking for decreases in their bad cholesterol, blood pressure and weight, as well as whether their diet and clinical attendance improved.

A few European studies have found that patients saw improved outcomes after they were told about test results confirming a genetic predisposition for a particular disease. These findings raise the question of whether people react more to genetic information than to other criteria used in diagnoses. “It’s a concept called genetic exclusivity,” said

Knowles. “It’s surprising and not necessarily intuitive."

More information: The trial is registered at clinicaltrials.gov and is currently supported by a seed grant from Spectrum, the Stanford Center for Clinical and Translational Education and Research, which is funded by a National Institutes of Health

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