

NIH launches trial to evaluate anti-inflammatory treatment for preventing heart attacks, strokes, and cardiovascular death

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An international multi-site trial has launched to determine whether a common anti-inflammatory drug can reduce heart attacks, strokes, and deaths due to cardiovascular disease in people at high risk for them. This study is being supported by the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health.

Inflammation, along with high blood pressure and [high cholesterol](#), plays a major role in [heart attack](#) and stroke. The Cardiovascular Inflammation Reduction Trial (CIRT) will determine whether treatment with a drug specifically targeting inflammation reduces rates of [cardiovascular events](#) among adults who have had a heart attack within the past five years and who also have [type 2 diabetes](#) or metabolic syndrome. The trial will randomly assign participants to receive methotrexate given at 10 to 20 milligrams weekly for three to four years or a placebo. Methotrexate is an inexpensive generic drug commonly used at low doses to treat [rheumatoid arthritis](#). It is also used at higher doses to treat certain forms of cancers such as leukemias and lymphomas.

"This trial could have global impact by potentially changing treatment recommendations for millions of individuals with heart disease," said Gary H. Gibbons, M.D., director of the NHLBI.

Each year, over 2 million people in the United States have heart attacks

or strokes, and many of them die. "If this generic drug, which is already on the market at low cost, proves effective for reducing risk of heart attacks, stroke, or death, it has the potential for broad public health impact in saving lives and reducing disease," said Paul Ridker, M.D., M.P.H., an expert in inflammation biology as it relates to heart attack and stroke. Dr. Ridker, who will serve as principal investigator for CIRT, is the Eugene Braunwald Professor of Medicine at Harvard Medical School, and director of the Center for Cardiovascular Disease Prevention at the Brigham and Women's Hospital, Boston.

Adults who have type 2 diabetes are much more likely to die of heart disease or stroke than people without type 2 diabetes. Metabolic syndrome—a cluster of traits that includes a large waistline, [high blood pressure](#), high levels of blood triglyceride (a type of fat), high blood sugar, and low blood HDL (the good cholesterol)—also raises the risk of heart attack and stroke. Many people with type 2 diabetes and obesity also have metabolic syndrome. People with diabetes or metabolic syndrome typically have elevated blood levels of various markers of inflammation.

CIRT will enroll 7,000 patients at 350-400 sites across the United States and Canada over the next 2.5 years and will follow them for two to four years (average 2.5 years). Site selection will begin in November 2012, and patient recruitment will start in March 2013.

Eligible participants who tolerate the drug without side effects over a five-week test period will be randomly assigned to receive standard care plus placebo or standard care plus low-dose methotrexate. Participants will also take folic acid, which is routinely given with methotrexate to prevent vitamin deficiencies.

In addition to measuring the number of strokes, heart attacks, and heart-related deaths among participants, CIRT will determine if low-dose

methotrexate reduces death from all causes and certain heart- and blood vessel-related conditions and events, including incident deep vein thrombosis, pulmonary embolism, atrial fibrillation, hospitalization for chest pain or congestive [heart](#) failure, non-surgical procedures or coronary artery bypass surgery, and newly diagnosed type 2 diabetes. CIRT will also establish a [blood](#) and DNA bank to study the effect of low-dose methotrexate on a number of inflammatory biomarkers.

More information: CIRT is funded by the NHLBI grants 1 U01 HL101422-01A1 (Clinical Coordinating Center) and 1 U01 HL101389-01A1 (Data Coordinating Center).

Find out more about CIRT at clinicaltrials.gov/ct2/show/NCT01594333 and at www.thecirt.org/

Provided by NIH/National Heart, Lung and Blood Institute

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