

SHORT TITLE: PROMINENT

RESEARCH PROTOCOL TITLE: Pemafibrate to Reduce cardiovascular Outcomes by reducing triglycerides IN diabetic patients

CONDITION TAGS: Heart, Diabetes Type 2

PRINCIPAL INVESTIGATOR: Matt Wolff, MD

RESEARCH SPONSOR: Kowa Research Institute

Clinical Trials.Gov Listing at:

STUDY PURPOSE

The purpose of this study is to find out if the study drug along with standard care helps lower the incidence of heart attack, heart pain, stroke or death in patients with Type-2 diabetes. Half of the research subjects will receive the study drug. The other half of the subjects will receive a placebo (a pill that looks like the medicine but contains no active ingredients).

STUDY PROCEDURES

The study will last between 3 and 5 years with study visits every 6 months after the first year. Phone call visits will be conducted in between clinic visits. There are more frequent visits the first year of the study. During the study visits vital signs (weight, blood pressure and pulse) will be taken, questionnaires completed, and study medication will be collected and re-dispensed. Some visits will include a physical exam by a study doctor.

ELIGIBILITY CRITERIA FOR SUBJECTS

1. Be willing to give informed consent
2. Be 50 (male) or 55 (female) years or older
3. Have a diagnosis of Diabetes Mellitus Type 2
4. Have established risk factors for cardiovascular disease or
5. Be at risk for cardiovascular disease

SUBJECT PAYMENT

Participants will be compensated \$50 (fifty) for each completed study visit.

RESEARCH LOCATION AND CONTACT PERSON

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