

CIRT TRIAL

A Randomized, Double-blind, Placebo-controlled, Event-driven trial of Weekly Low-dose Methotrexate (LDM) in the Prevention of Recurrent Cardiovascular Events Among Stable Post-Myocardial Infarction Patients with Type 2 Diabetes or Metabolic Syndrome .

Study Phase III

Purpose

The purpose of the study is whether taking low-dose methotrexate reduces heart attacks, strokes, or death in people with type 3 diabetes or metabolic syndrome that have had a heart attack. This trial is funded by the National Heart, Lung, and Blood Institute (NHLBI)/National Institutes of Health (NIH).

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria:

- Male & Females of 18 years old and older
- Documented myocardial infarction within the past 5 years AND
- Type 2 diabetes AND/OR metabolic syndrome
- Completed any planned coronary revascularization procedures
- Medically stable for at least 60 days prior to screening

Exclusion Criteria:

- Chronic liver disease, inflammatory conditions such as lupus or rheumatoid arthritis, ulcerative colitis or Crohn's disease
- Chronic infectious disease, HIV positive
- Interstitial lung disease or pulmonary fibrosis
- Myeloproliferative disease in the past 5 years
- Requirement for, or intolerance to, methotrexate or folate
- History of non-basal cell malignancy or treatment for lymphoproliferative disease in past 5 yrs
- Requirement for the use of drugs that alter folate metabolism

To inquire if you are eligible for this study or hear more about it, please contact:

**Pentucket Medical Associates
Clinical Research Office
(978) 469-5494**