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Colchicine Cardiovascular Outcomes Trial (COLCOT) (COLCOT)

This study is currently recruiting participants.

See Contacts and Locations

Verified March 2017 by Montreal Heart Institute

Sponsor:
Montreal Heart Institute

ClinicalTrials.gov Identifier:
NCT02551094

First Posted: September 16, 2015
Last Update Posted: March 8, 2017

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Information provided by (Responsible Party):
Montreal Heart Institute

Purpose

The study evaluates whether long-term treatment with colchicine reduces rates of cardiovascular events in patients after myocardial infarction. Patients who have suffered a documented acute myocardial infarction within the last 30 days, are treated according to the national guidelines and after having completed any planned percutaneous revascularization procedures associated with their initial infarction will receive either colchicine (0.5 mg per day) or matching placebo (1:1 allocation ratio) for an estimated 2 years period or until the target of 301 primary endpoints has been reached.

Condition	Intervention	Phase
Coronary Artery Disease Myocardial Infarction	Drug: colchicine Drug: colchicine placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Prevention

Official Title: Colchicine Cardiovascular Outcomes Trial (COLCOT)

Resource links provided by NLM:

MedlinePlus related topics: Heart Attack

Drug Information available for: Colchicine

U.S. FDA Resources

Further study details as provided by Montreal Heart Institute:

Primary Outcome Measures:

- Cardiovascular death [Time Frame: approximately 3 to 4 years]
  number of days from randomization
- resuscitated cardiac arrest [Time Frame: approximately 3 to 4 years]
  number of days from randomization
- acute myocardial infarction [Time Frame: approximately 3 to 4 years]
  number of days from randomization
- stroke [Time Frame: approximately 3 to 4 years]
  number of days from randomization
- hospitalization for angina requiring coronary revascularization [Time Frame: approximately 3 to 4 years]
  number of days from randomization

Secondary Outcome Measures:

- total mortality [Time Frame: approximately 3 to 4 years]
  number of days from composite of cardiovascular death

- total mortality [Time Frame: approximately 3 to 4 years]

  number of days from composite of resuscitated cardiac arrest

- total mortality [Time Frame: approximately 3 to 4 years]

  number of days from composite of acute myocardial infarction

- total mortality [Time Frame: approximately 3 to 4 years]

  number of days from composite of stroke

Other Outcome Measures:

- deep venous thrombosis [Time Frame: approximately 3 to 4 years]

  number of days from randomization

- pulmonary embolus [Time Frame: approximately 3 to 4 years]

  number of days from randomization

- atrial fibrillation [Time Frame: approximately 3 to 4 years]

  number of days from randomization

- heart failure hospitalization [Time Frame: approximately 3 to 4 years]

  number of days from randomization

- coronary revascularization [Time Frame: approximately 3 to 4 years]

  number of days from randomization

Estimated Enrollment:	4500
Study Start Date:	September 2015
Estimated Study Completion Date:	September 2019
Estimated Primary Completion Date:	March 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: colchicine 0.5 mg tablet of colchicine taken once a day	Drug: colchicine 0.5 mg tablet taken once a day Other Name: no other name
Placebo Comparator: colchicine placebo 0.5 mg tablet of placebo taken once a day	Drug: colchicine placebo sugar pill manufactured to mimic colchicine 0.5 mg tablet Other Name: no other name

Detailed Description:

Atherosclerosis is the most common cause of myocardial infarction, stroke and peripheral arterial disease. Research has clearly demonstrated that inflammation plays a key role in the initiation, progression and manifestations of atherosclerosis. Atherosclerotic lesions begin as an accumulation of lipid-laden cells (primarily macrophages) beneath the endothelium, and progress with the further accumulation of cells, connective-tissue elements, lipids and debris through immunological and inflammatory activation. Neutrophils and other inflammatory cells have been shown to invade culprit atherosclerotic lesions in acute coronary syndromes. It is likely that the inflammatory process is responsible for the high rate of cardiovascular events despite significant advances in the treatment of risk factors such as hypercholesterolemia and hypertension. It is vital to improve our understanding of the inflammatory nature of atherosclerotic disease and modify the inflammatory process with targeted therapies. Prospective cohort studies have consistently shown that high sensitivity C-reactive protein (hs-CRP) and several other biomarkers of inflammation are independently associated with increasing risk of future cardiovascular events in different populations. This together with animal models showing that reduced inflammation has anti-atherosclerotic effects, create the impetus to test the hypothesis that treatment of the underlying inflammatory process will contribute to improved cardiovascular clinical outcomes. Colchicine is an inexpensive, yet potent, anti-inflammatory drug approved for acute use in patients with gout and chronic use in patients with Familial Mediterranean Fever. The mechanism of action is through the inhibition of tubulin polymerization and potentially also through effects on cellular adhesion molecules and inflammatory chemokines. Colchicine may also have direct anti-inflammatory effects by inhibiting key inflammatory signaling networks known as the inflammasome and pro-inflammatory cytokines. Through the disruption of the cytoskeleton, colchicine is believed to suppress secretion of cytokines and chemokines as well as in vitro platelet aggregation. Considerable work has highlighted the potential of colchicine in the treatment of cardiovascular diseases mediated by pro-inflammatory processes. More recently colchicine has been evaluated for its effect on cardiovascular events in patients with coronary artery disease (CAD).

Eligibility

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Males and females of at least 18 years of age capable and willing to provide informed consent
- Patient must have suffered a documented acute myocardial infarction within the last 30 days
- Patient must be treated according to national guidelines (including anti-platelet therapy, statin, renin-angiotensin-aldosterone system inhibitor (preferably angiotensin-converting enzyme) and beta-blocker when indicated)
- Patient must have completed any planned percutaneous revascularization procedures associated with his or her qualifying myocardial infarction
- Female patient is either not of childbearing potential, defined as postmenopausal or is of childbearing potential and practicing at least one method of contraception and preferably two complementary forms of contraception
- Patient is judged to be in good general health as determined by the principal investigator
- Patient must be able and willing to comply with the requirements of this study protocol

Exclusion Criteria:

- Patient with a poorly controlled medical condition, such as New York Heart Association Class III-IV heart failure, a left ventricular ejection fraction of less than 35%, recent stroke (within the past 3 months), or any other condition which in the opinion of the investigator, would put the patient at risk if participating in this study
- Patient with a prior coronary artery bypass graft within the past 3 years, or planned
- Patient currently in cardiogenic shock or with hemodynamic instability
- Patient with a history of cancer or lymphoproliferative disease within the last 3 years other than a successfully treated non-metastatic cutaneous squamous cell or basal cell carcinoma and or localized carcinoma in situ of the cervix
- Patient with inflammatory bowel disease (Crohn's disease or ulcerative colitis) or patient with chronic diarrhea
- Patient with pre-existent progressive neuromuscular disease or patient with creatine phosphokinase level greater than 3 times the upper limit of normal (unless due to myocardial infarction which is allowed) as measured within the past 30 days and determined to be non-transient through repeat testing
- Patient with any of the following as measured within the past 30 days, and determined to be non-transient through repeat testing: hemoglobin less than 115 grams/L, white blood cell count less than 3.0 X 10(9)/L,platelet count less than 110 X 10(9)/L, alanine aminotransferase greater than 3 times the upper limit of normal, total bilirubin greater than 2 times the upper limit of normal (unless due to Gilbert syndrome, which is allowed), creatinine greater than 2 times the upper limit of normal
- Patient with a history of cirrhosis, chronic active hepatitis or sever hepatic disease
- Female patient who is pregnant, or breast-feeding or is considering becoming pregnant during the study or for 6 months after the last dose of study medication
- Patient with a history of clinically significant drug or alcohol abuse in the last year
- Patient is currently using or plan to begin chronic systemic steroid therapy (oral or intravenous) during the study (topical or inhaled steroids are allowed)
- Patient currently taking colchicine for other indications (mainly chronic indications represented by Familial Mediterranean Fever or gout); there is no wash-out period required for patients who have been treated with colchicine and stopped treatment prior to enrollment
- Patient with history of an allergic reaction or significant sensitivity to colchicine
- Patient who has used an investigational chemical agent less than 30 days or 5 half-lives prior to the screening visit (whichever is longer)
- Patient is considered by he investigator, for any reason, to be an unsuitable candidate for the study

Contacts and Locations

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02551094***

Contacts

Contact: Jean-Claude Tardif, MD 514 376-3330 ext 3612 jean-claude.tardif@icm-mhi.org

Contact: Mylène Provencher, MSc 514 461-1300 ext 2133 mylene.provencher@mhicc.org

Locations

Canada, Quebec

Montreal Heart Institute **Recruiting**
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Principal Investigator: Jean-Claude Tardif, MD
Sub-Investigator: Philippe L L'Allier, MD

Sponsors and Collaborators

Montreal Heart Institute

Investigators

Principal Investigator: Jean-Claude Tardif, MD Montreal Heart Institute

More Information

Responsible Party:	Montreal Heart Institute
ClinicalTrials.gov Identifier:	NCT02551094 History of Changes
Other Study ID Numbers:	MHIPS-003
First Submitted:	August 26, 2015
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Additional relevant MeSH terms:

Infarction
Coronary Artery Disease
Myocardial Ischemia
Coronary Disease
Myocardial Infarction
Ischemia
Pathologic Processes
Necrosis
Heart Diseases
Cardiovascular Diseases
Arteriosclerosis
Arterial Occlusive Diseases
Vascular Diseases
Colchicine
Gout Suppressants
Antirheumatic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents