



Record 1 of 2



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COMPLETED ⓘ

Colchicine Cardiovascular Outcomes Trial (COLCOT) (COLCOT)

ClinicalTrials.gov ID ⓘ NCT02551094

Sponsor ⓘ Montreal Heart Institute

Information provided by ⓘ Montreal Heart Institute (Responsible Party)

Last Update Posted ⓘ 2020-10-19

Study Details Tab

Study Overview

Brief Summary

Feedback

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.

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).

Official Title

Colchicine Cardiovascular Outcomes Trial (**COLCOT**)

Conditions ⓘ

Coronary Artery Disease

Myocardial Infarction

Intervention / Treatment ⓘ

- Drug: colchicine
- Drug: colchicine placebo

Other Study ID Numbers ⓘ

- MHIPS-003

Study Start (Actual) ⓘ

2015-12-04

Primary Completion (Actual) ⓘ

2019-07-17

Study Completion (Actual) ⓘ

2019-07-17

Enrollment (Actual) ⓘ

4745

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>), related topics: [Heart Attack](https://medlineplus.gov/heartattack.html) (<https://medlineplus.gov/heartattack.html>).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for: [Colchicine](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Colchicine) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Colchicine>).

[Other U.S. FDA Resources](https://classic.clinicaltrials.gov/ct2/info/fdalinks) (<https://classic.clinicaltrials.gov/ct2/info/fdalinks>).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Canada

Quebec Locations

 **Montreal, Quebec, Canada, H1T1C8**
Montreal Heart Institute

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

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 for at least one year or surgically sterile, 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 Type 2 index MI (secondary to ischemic imbalance)
- 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 $3.0 \times 10^9/L$, platelet count less than $110 \times 10^9/L$, 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 severe 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 the investigator, for any reason, to be an unsuitable candidate for the study

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Prevention

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm i	Intervention/Treatment i
Active Comparator: colchicine 0.5 mg tablet of colchicine taken once a day	Drug: colchicine 0.5 mg tablet taken once a day - Other Names: - 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 Names: - no other name

What is the study measuring?

Primary Outcome Measures i

Outcome Measure	Measure Description	Time Frame
First Event of Cardiovascular Death, Resuscitated Cardiac Arrest, Acute Myocardial Infarction, Stroke, or Urgent Hospitalization for Angina Requiring	The descriptive statistics are the number of participants having at least one of the composites of the primary endpoint.	From randomization to occurrence of first event, assessed up to 3.5 years

Coronary
Revascularization

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Death (Total Mortality)	The descriptive statistics are the number of participants having deceased.	From randomization to death, assessed up to 3.5 years
Cardiovascular Death	The descriptive statistics are presented as the number of participants having had a cardiovascular death.	From randomization to death, assessed up to 3.5 years
Resuscitated Cardiac Arrest	The descriptive statistics are presented as the number of participants having had resuscitated cardiac arrest	From randomization to event, assessed up to 3.5 years
Myocardial Infarction	The descriptive statistics are presented as the number of participants having had myocardial infarction.	From randomization to event, assessed up to 3.5 years
Stroke	The descriptive statistics are presented as the number of participants having had a stroke.	From randomization to event,

		assessed up to 3.5 years
Urgent Hospitalization for Angina Requiring Coronary Revascularization	The descriptive statistics are presented as the number of participants having had urgent hospitalization for angina requiring coronary revascularization.	From randomization to event, assessed up to 3.5 years
First Event of Cardiovascular Death, Resuscitated Cardiac Arrest, Acute MI or Stroke.	The descriptive statistics are presented as the number of participants having had a first event of cardiovascular death, resuscitated cardiac arrest, acute MI or stroke.	From randomization to occurrence of first event, assessed up to 3.5 years

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
First Event of Deep Venous Thrombosis or Pulmonary Embolus	The descriptive statistics are presented as the number of participants having had a first event of deep venous thrombosis or pulmonary embolus.	From randomization to occurrence of first event, assessed up to 3.5 years
Atrial Fibrillation	The descriptive statistics are presented as the number of participants having had atrial fibrillation.	From randomization to event, assessed up to 3.5 years

Heart Failure Hospitalization	The descriptive statistics are presented as the number of participants having had heart failure hospitalization.	From randomization to event, assessed up to 3.5 years
Coronary Revascularization	The descriptive statistics are presented as the number of participants having had coronary revascularization.	From randomization to event, assessed up to 3.5 years

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Montreal Heart Institute

Collaborators ⓘ

No information provided

Investigators ⓘ

- Principal Investigator: Jean-Claude Tardif, MD, Montreal Heart Institute
- Study Director: Andreas Orfanos, MD, Montreal Health Innovations Coordinating Centre

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

* Find [Publications about Study Results](#) and related [Pubmed Publications](#) in the “Results” section of the study record.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2015-08-26

First Submitted that Met QC Criteria ⓘ

2015-09-14

First Posted (Estimated) ⓘ

2015-09-16

Results Reporting Dates

Results First Submitted ⓘ

2020-07-17

Results First Submitted that Met QC Criteria ⓘ

2020-09-23

Results First Posted ⓘ

2020-10-19

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2020-09-23

Last Update Posted ⓘ

2020-10-19

Last Verified ⓘ

2020-09

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

Drug and device information, study documents, and helpful links

Study Documents ⓘ

- [Statistical Analysis Plan \(https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/SAP_000.pdf\)](https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/SAP_000.pdf). [PDF, 0.92MB, 2019-08-28]
- [Study Protocol \(https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/Prot_001.pdf\)](https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/Prot_001.pdf). [PDF, 0.81MB, 2018-11-15]