

Record 12 of 271



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COMPLETED 

Colchicine Cardiovascular Outcomes Trial (COLCOT) (COLCOT)

ClinicalTrials.gov ID  NCT02551094Sponsor  Montreal Heart InstituteInformation provided by  Montreal Heart Institute (Responsible Party)Last Update Posted  2020-10-19

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2015-09-14	None (earliest version on record)
Compare			

Feedback 

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	2	2015-12-10	- Recruitment Status - Study Status - Contacts/Locations
☐	3	2017-03-06	- Study Status - Study Identification - Contacts/Locations
☐	4	2018-06-13	Study Status
☐	5	2018-11-15	- Recruitment Status - Study Status - Study Design
☐	6	2018-12-17	Study Status
☐	7	2019-04-09	Study Status
☐	8	2019-10-12	- Recruitment Status - Study Status - Eligibility - Outcome Measures
☐	9	2020-02-20	- Study Status - Contacts/Locations
☐	10	2020-09-23	- Study Status - Outcome Measures - Participant Flow - Baseline Characteristics - Adverse Events - More Information - Document Section

Study Details

Study Identification

Unique Protocol ID
MHIPS-003
Brief Title
Colchicine Cardiovascular Outcomes Trial (COLCOT)
Official Title
Colchicine Cardiovascular Outcomes Trial (COLCOT)
Secondary IDs

Study Status

Record Verification
2020-09
Overall Status
Completed
Study Start
2015-12-04 [Actual]
Primary Completion
2019-07-17 [Actual]
Study Completion
2019-07-17 [Actual]
First Submitted
2015-08-26

First Submitted that Met QC Criteria
2015-09-14
First Posted
2015-09-16
Results First Submitted
2020-07-17
Results First Submitted That Met QC Criteria
2020-09-23
Results First Posted
2020-10-19
Last Update Submitted that Met QC Criteria
2020-09-23
Last Update Posted
2020-10-19 [Actual]

Sponsor/Collaborators

Sponsor
Montreal Heart Institute
Responsible Party
Sponsor
Collaborators

Oversight

U.S. FDA-regulated Drug
U.S. FDA-regulated Device

Data Monitoring
Yes

Study Description

Brief Summary
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).

Conditions

Condition
Coronary Artery Disease Myocardial Infarction
Keywords

Study Design

Study Type
Interventional
Primary Purpose
Prevention
Study Phase
Phase 3

Interventional Study Model
Parallel Assignment
Interventional Model Description
Number of Arms
2
Masking
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description
Allocation
Randomized
Enrollment
4745 [Actual]

Arms and Interventions

Arms	Assigned Interventions 
Active Comparator: colchicine 0.5 mg tablet of colchicine taken once a day	Drug: colchicine • 0.5 mg tablet tak day • Other Names: ◦ no other n
Placebo Comparator: colchicine placebo 0.5 mg tablet of placebo taken once a day	Drug: colchicine placeb • sugar pill manufa mimic colchicine tablet • Other Names: ◦ no other n 



Outcome Measures

Primary Outcome Measures

1. First Event of Cardiovascular Death, Resuscitated Cardiac Arrest, Acute Myocardial Infarction, Stroke, or Urgent Hospitalization for Angina Requiring Coronary Revascularization

The descriptive statistics are the number of participants having at least one of the composites of the primary endpoint.

[Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years]

Secondary Outcome Measures

1. Death (Total Mortality)

The descriptive statistics are the number of participants having deceased.

[Time Frame: From randomization to death, assessed up to 3.5 years]

2. Cardiovascular Death

The descriptive statistics are presented as the number of participants having had a cardiovascular death.

[Time Frame: From randomization to death, assessed up to 3.5 years]

3. Resuscitated Cardiac Arrest

The descriptive statistics are presented as the number of participants having had resuscitated cardiac arrest

[Time Frame: From randomization to event, assessed up to 3.5 years]

4. Myocardial Infarction

The descriptive statistics are presented as the number of participants having had myocardial infarction.

[Time Frame: From randomization to event, assessed up to 3.5 years]

5. Stroke

The descriptive statistics are presented as the number of participants having had a stroke.

[Time Frame: From randomization to event, assessed up to 3.5 years]

6. 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.

[Time Frame: From randomization to event, assessed up to 3.5 years]

7. 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.

[Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years]

Other Outcome Measures

1. 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.

[Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years]

2. Atrial Fibrillation

The descriptive statistics are presented as the number of participants having had atrial fibrillation.

[Time Frame: From randomization to event, assessed up to 3.5 years]

3. Heart Failure Hospitalization

The descriptive statistics are presented as the number of participants having had heart failure hospitalization.

[Time Frame: From randomization to event, assessed up to 3.5 years]

4. Coronary Revascularization

The descriptive statistics are presented as the number of participants having had coronary revascularization.

[Time Frame: From randomization to event, assessed up to 3.5 years]

Eligibility

Minimum Age
18 Years

Maximum Age

Sex
All

Gender-based Eligibility

Gender Eligibility Description

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 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

Contacts/Locations

Central Contact Person

Study Officials

- Name
Jean-Claude Tardif, MD

Role
Principal Investigator

Affiliation
Montreal Heart Institute
- Name
Andreas Orfanos, MD

Role
Study Director

Affiliation
Montreal Health Innovations Coordinating Centre

Location

- **Montreal, Quebec, Canada, H1T1C8**

Facility:
Montreal Heart Institute

IPD Sharing

Available IPD/Information
IPD information

References

Citations
Links

Document Section

Study Protocol
• Document Label Study Protocol Date 2018-11-15 Uploaded 2020-07-16 15:14 File name Prot_001.pdf (https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/Prot_001.pdf)
Statistical Analysis Plan
• Document Label Statistical Analysis Plan

Date

2019-08-28

Uploaded

2020-07-16 15:12

File name

[SAP_000.pdf \(https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/SAP_000.pdf\)](https://storage.googleapis.com/ctgov2-large-docs/94/NCT02551094/SAP_000.pdf)

Study Results

Participant Flow

Recruitment Details
[Not Specified]
Pre-assignment Details
[Not Specified]

Arm/Group Title	Colchicine	
Arm/Group Description	0.5 mg tablet of colchicine taken once a day colchicine: 0.5 mg tablet taken...	0 o c

Started	2366	
Completed	2226	
Not Completed	140	



Baseline Characteristics

Arm/Group Title	Colchicine	
Arm/Group Description	0.5 mg tablet of colchicine taken once a day colchicine: 0.5 mg tablet taken...	0 o c
Overall Number of Baseline Participants	2366	
Baseline Analysis Population Description	[Not Specified]	

[Expand all](#) / [Collapse all](#)

Number Analyzed	2366 participants	
	60.6 (10.7)	

Number Analyzed	2366 participants	
Female	472 19.9%	
Male	1894 80.1%	

Number Analyzed	2366 participants	
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Ethnic Origin

Asian	26 1.1%	
Asian and Caucasian	1 0.0%	

Black or African American	3	0.1%
Black or African American and Caucasian	1	0.0%
Black or African American and Hispanic or Latino	1	0.0%
Caucasian	1350	57.1%
Caucasian and Hispanic or Latino	17	0.7%
Hispanic or Latino	377	15.9%
Indian ancestry	1	0.0%
Metis, aboriginal	0	0.0%
Native American	3	0.1%
North African / Middle Eastern	70	3.0%
France n=1051 (Ethnic origin was not provided)	516	21.8%

Number Analyzed	2366 participants	
Argentina	230	9.7%
Canada	739	31.2%
Chile	111	4.7%
Colombia	82	3.5%

France	516	21.8%
Germany	6	0.3%
Italy	270	11.4%
Lebanon	92	3.9%
Portugal	111	4.7%
Spain	32	1.4%
Tunisia	100	4.2%
United Kingdom	77	3.3%

Outcome Measures

[Expand all](#) / [Collapse all](#)

1. First Event of Cardiovascular Death, Resuscitated Cardiac Arrest, Acute Myocardial Infarction, Stroke, or Urgent Hospitalization for Angina Requiring Coronary Revascularization

Type: Primary | Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years

Description	The descriptive statistics are the number of participants having at least one of the composites of the primary endpoint.
Time Frame	From randomization to occurrence of first event, assessed up to 3.5 years
Analysis Population Description	[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	170 7.1%	

2. Death (Total Mortality)

Type: Secondary | Time Frame: From randomization to death, assessed up to 3.5 years

Description	The descriptive statistics are the number of participants having deceased.	
Time Frame	From randomization to death, assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	44 1.8%	

3. Cardiovascular Death

Type: Secondary | Time Frame: From randomization to death, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had a cardiovascular death.	
Time Frame	From randomization to death, assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	24 1.0%	

4. Resuscitated Cardiac Arrest

Type: Secondary | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had resuscitated cardiac arrest	
Time Frame	From randomization to event,	

	assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	6 0.3%	

5. Myocardial Infarction

Type: Secondary | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had myocardial infarction.
Time Frame	From randomization to event, assessed up to 3.5 years
Analysis Population Description	[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	98 4.1%	

6. Stroke

Type: Secondary | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had a stroke.	
Time Frame	From randomization to event, assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	19 0.8%	

7. Urgent Hospitalization for Angina Requiring Coronary Revascularization

Type: Secondary | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had urgent hospitalization for angina requiring coronary revascularization.	
Time Frame	From randomization to event, assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	50 2.1%	

8. First Event of Cardiovascular Death, Resuscitated Cardiac Arrest, Acute MI or Stroke.

Type: Secondary | Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had a first event	
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	of cardiovascular death, resuscitated cardiac arrest, acute MI or stroke.	
Time Frame	From randomization to occurrence of first event, assessed up to 3.5 years	
Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	130 5.5%	

9. First Event of Deep Venous Thrombosis or Pulmonary Embolus

Type: Other Pre-specified | Time Frame: From randomization to occurrence of first event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had a first event of deep venous thrombosis or pulmonary embolus.
Time Frame	From randomization to occurrence of first event, assessed up to 3.5 years

Analysis Population Description	[Not Specified]	
Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	7	0.3%

10. Atrial Fibrillation

Type: Other Pre-specified | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had atrial fibrillation.
Time Frame	From randomization to event, assessed up to 3.5 years
Analysis Population Description	[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	40 1.7%	

11. Heart Failure Hospitalization

Type: Other Pre-specified | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had heart failure hospitalization.
Time Frame	From randomization to event, assessed up to 3.5 years
Analysis Population Description	[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	18 0.8%	

12. Coronary Revascularization

Type: Other Pre-specified | Time Frame: From randomization to event, assessed up to 3.5 years

Description	The descriptive statistics are presented as the number of participants having had coronary revascularization.
Time Frame	From randomization to event, assessed up to 3.5 years
Analysis Population Description	[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c
Overall Number of Participants Analyzed	2379	
Measure Type: Count of Participants Unit of Measure: Participants	164 6.9%	

Adverse Events

Time Frame

The time period covered was from randomization to last follow up which lasted 3.5 years.

Adverse Event Reporting Description

[Not Specified]

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c

[Expand all](#) / [Collapse all](#)

Arm/Group Title	Colchicine Placebo	
	Affected / at Risk (%)	
Total	44/2346 (1.88%)	

Arm/Group Title	Colchicine Placebo	
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...	0 o c

Arm/Group Title	Colchicine Placebo		A
	Affected / at Risk (%)	# Events	
Total	404/2346 (17.22%)		

Cardiac disorders

HF hospitalization SAE [†]	17/2346 (0.72%)	371	
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Gastrointestinal disorders

Gastro-intestinal SAE [†]	36/2346 (1.53%)	404	
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General disorders

Other [†]	319/2346 (13.60%)	404	
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Infections and infestations

Infection SAE [†]	38/2346 (1.62%)	404	
Septic Shock SAE [†]	2/2346 (0.09%)	404	2

Respiratory, thoracic and mediastinal disorders

Pneumonia SAE [†]	9/2346 (0.38%)	404	
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Arm/Group Title	Colchicine Placebo		
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...		0 o c
† Indicates events were collected by systematic assessment			

Frequency Threshold for Reporting Other Adverse Events	0%		
Arm/Group Title	Colchicine Placebo		
	Affected / at Risk (%)	# Events	A
Total	371/2346 (15.81%)		

Blood and lymphatic system disorders

Anaemia AE [†]	10/2346 (0.43%)	371	
Leukopenia AE [†]	3/2346 (0.13%)	371	2
Thrombocytopenia AE [†]	7/2346 (0.30%)	371	3

Gastrointestinal disorders

Nausea AE [†]	24/2346 (1.02%)	371	
Flatulence AE [†]	5/2346 (0.21%)	371	

Arm/Group Title	Colchicine Placebo		
Arm/Group Description	0.5 mg tablet of placebo taken once a day colchicine placebo: sugar pill...		0 o c
GI Haemorrhage AE [†]	5/2346 (0.21%)	371	7

General disorders

Other [†]	109/2346 (4.65%)	371	
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Metabolism and nutrition disorders

Diarrhea AE [†]	208/2346 (8.87%)	371	
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[†] Indicates events were collected by systematic assessment

Limitations and Caveats

Description
[Not Specified]

More Information

Certain Agreements
Principal investigators are NOT employed by the organization sponsoring the study. The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time

submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact	
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