



CREATE ACCOUNT

LOGIN



DEFINITIONS



HINTS AND TIPS



FAQs



REGISTER TRIAL



MY TRIALS

Trial Review

To achieve prospective registration, we recommend submitting your trial for registration at the same time as ethics submission.

Registering a new trial?

Videos on how to complete [Step 3: Intervention](#), [Step 4: Outcomes](#) and [Step 11: Data sharing](#) are available.

We have now released the latest update to our report on [the clinical trials landscape in Australia \(2006 – 2020\)](#), which outlines key characteristics of clinical trials over time.

VIEW TRIAL AT REGISTRATION

VIEW HISTORY

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 endorsed by the ANZCTR. Before participating in a study, talk to your health care provider and refer to this [information for consumers](#)

< BACK

Trial registered on ANZCTR

Registration number	ACTRN12616000400460
Ethics application status	Approved
Date submitted	7/03/2016
Date registered	29/03/2016
Date last updated	8/07/2022
Date data sharing statement initially provided	18/03/2019
Type of registration	Prospectively registered

Titles & IDs

Public title	The effect of Colchicine on Cardiovascular Outcomes in Acute Coronary Syndrome Study (The COLCARDIO-ACS Study)
Scientific title	The COLCARDIO-ACS Study - Colchicine Cardiovascular Outcomes in Acute Coronary Syndrome Study
Secondary ID [1]	None
Universal Trial Number (UTN)	U1111-1180-4572
Trial acronym	COLCARDIO-ACS COLCHICINE-COG (sub study)
Linked study record	

Health condition

Health condition(s) or problem(s) studied:

Acute coronary syndrome

Ischaemic heart disease

Atherosclerosis

Condition category

Cardiovascular

Condition code

Coronary heart disease

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	Oral Colchicine 0.5 mg tablet taken daily for median of 3 years. Eligible and consenting participants will be registered and then commenced on Run-In treatment consisting of 1 oral tablet (0.5mg of colchicine) a day for 28 days additional to standard of care medication prescribed by treating physician. The Run-In treatment will be dispensed to participants in a single blinded manner. Upon completion of the Run-In treatment participants will be asked to return to site for a safety and compliance check before being randomised to receive either oral Colchicine 0.5mg taken daily or matched oral Placebo tablet taken daily for a median of 3 years and 600 primary endpoint events have occurred. Ongoing study treatment will be dispensed on a 6 monthly basis and participants will attend annual in clinic visits for clinical assessments and compliance check. Eligible and consenting participants to the COLCHICINE-COG sub study will have additional assessments including 30-minute online neuropsychological assessments (baseline, 12, 24 and 36 months), blood collection performed at the same time as collection for the main study (baseline, 12 and 36 months) and 30-60 minute MRI assessments in a sub-set of participants (n=40) at baseline and 12 months.
Intervention code [1]	Treatment: Drugs
Comparator / control treatment	Matched oral Placebo tablet taken daily for median 3 years. These tablets will be sugar pills with no active medicine.
Control group	Placebo
Outcomes	
Primary outcome [1]	The occurrence of major adverse cardiovascular events (MACE); a composite of ACS including myocardial infarction, urgent unscheduled revascularization, CV death, and non-fatal stroke, at 36 months The outcome will assess incidence using, regular follow-up and self reported events or hospitalisations, reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [1]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months (primary timepoint) and annually until end of study.
Primary outcome [2]	COLCHICINE-COG: Processing Speed assessed by the Rapid Visual Information Processing using the Cambridge Neuropsychological Test Automated Battery (CANTAB) Connect web-based testing
Timepoint [2]	Measurements taken at at baseline (prior run-in), 12, 24 and 36 months.
Secondary outcome [1]	Acute Coronary Syndrome (including non-fatal myocardial infarction) The outcome will assess incidence using, regular follow-up and self-reported events or hospitalisations, reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [1]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months and annually until end of study.
Secondary outcome [2]	Urgent revascularisation The outcome will assess incidence using, regular follow-up and self-reported events or hospitalisations, reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [2]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months and annually until end of study.
Secondary outcome [3]	Cardiovascular death – death due to any cardiac cause (e.g. myocardial infarction, heart failure, arrhythmia and sudden cardiac death) The outcome will assess incidence using reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists
Timepoint [3]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18

	months, 24 months, 30 months, 36 months and annually until end of study.
Secondary outcome [4]	Non-fatal stroke
	The outcome will assess incidence using regular follow-up and self-reported events or hospitalisations, reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [4]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months and annually until end of study.
Secondary outcome [5]	All-cause mortality
	The outcome will assess incidence using reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [5]	Follow-up visits during the study treatment period are planned at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months and annually until end of study.
Secondary outcome [6]	Change in hs-CRP assessed from blood tests
Timepoint [6]	Baseline visit and then follow-up visits during the study treatment period are planned at 3 months, 12 months, 36 months.
Secondary outcome [7]	Quality of Life assessed as a composite of EuroQoL EQ-5D-5L, WHODAS 2.0 scores
Timepoint [7]	Baseline visit and then follow-up visits during the study treatment period are planned at 6 months, 24 months, 36 months and annually until the end of study.
Secondary outcome [8]	Number of days alive and not in hospital
	This outcome will be assessed using regular follow-up and self-reported events or hospitalisations, reporting of events by family members or other contacts, review of patient medical records and admission summaries and correspondence from GPs and other specialists.
Timepoint [8]	Follow-up visits during the study treatment period are planned at 3 months, 12 months, 24 months, 36 months and end of study.
Secondary outcome [9]	COLCHICINE COG: Executive functioning assessed by the Intra-Extra Dimensional Set Shift using the CANTAB Connect web-based testing
Timepoint [9]	Measurements taken at at baseline (prior run-in), 12, 24 and 36 months.
Secondary outcome [10]	COLCHICINE COG: Memory and learning assessed by the Paired Associate Learning using the CANTAB Connect web-based testing
Timepoint [10]	Measurements taken at at baseline (prior run-in), 12, 24 and 36 months.
Secondary outcome [11]	COLCHICINE COG: Blood-based biomarkers of neurodegeneration including Ptau-181, plasma neurofilament light chain and AB42-40
Timepoint [11]	Measurements taken at at baseline (prior run-in), 12 and at End of study.
Secondary outcome [12]	COLCHICINE COG: Brain Oxidative stress assessed via the measurement of glutathione in the anterior and posterior cingulate cortex using magnetic resonance spectroscopy
Timepoint [12]	Measurements taken at at baseline (prior run-in) and 12 months.
Secondary outcome [13]	COLCHICINE COG: Regional brain volume (hippocampi and thalamus) assessed using magnetic resonance imaging
Timepoint [13]	Measurements taken at at baseline (prior run-in) and 12 months.
Secondary outcome [14]	COLCHICINE COG: White matter lesion volume by MRI assessment
Timepoint [14]	Measurements taken at at baseline (prior run-in) and 12 months.
Secondary outcome [15]	COLCHICINE COG: Fractional anisotropy and mean diffusivity of white matter tracts by MRI assessment
Timepoint [15]	Measurements taken at at baseline (prior run-in) and 12 months.

Eligibility

Key inclusion criteria

1. Patients aged equal or greater than 18 years
2. Presentation with an Acute Coronary Syndrome (defined as acute myocardial infarction, with or without electrocardiographic evidence of ST-segment elevation, or high-risk unstable angina) and commenced on optimal medical therapy
3. hs-CRP equal or greater than 2mg/L (at time of registration 4 - 52 weeks after discharge for an Acute Coronary Syndrome event)
4. Willing and able to comply with all study requirements, including treatment, timing and/or nature of required assessments

5. Signed written informed consent

COLCHICINE-COG Inclusion criteria:

1. Be enrolled in COLCARDIO-ACS;
2. Be aged 40 - 65 years (at the time of enrolment);
3. Be willing and able to comply with sub-study visit schedule and nature of required assessments; and
4. Provide signed written informed consent

Minimum age

18 Years

Maximum age

No limit

Gender

Both males and females

Can healthy volunteers participate?

No

Key exclusion criteria

1. Any known intolerance to Colchicine
2. Pre-existing Colchicine treatment within the last 3 months
3. Any known myopathy (any grade or myopathy in present or prior history within the last 3 months or CK >3 x upper limit of normal)
4. Severe liver disease or aminotransferase level > 3x upper limit of normal, within the last 3 months
5. Blood dyscrasia (white cell count or platelet count < lower limit of normal), within the last 3 months
6. Estimated glomerular filtration rate (eGFR) <45 mL/min per 1.73m² at time of registration
7. Prior or current therapy with a strong CYP3A4 inhibitor or inducer or calcineurin inhibitor
8. Active autoimmune disease or chronic inflammatory bowel disease (defined as any disease requiring long-term or frequent immunosuppression)
9. Haematological malignancy which remains uncured or antineoplastic therapy within the last 3 months
10. Concurrent illness, including severe infection that may jeopardise the ability of the patient to undergo the procedures outlined in this protocol with reasonable safety
11. Any known comorbidities or conditions (e.g. psychiatric) or concomitant medications which may interact with the investigational product(s) or may compromise assessment of key outcomes.
12. Life expectancy of less than 3 years
13. Serious medical or psychiatric conditions that might limit the ability of the patient to comply with the protocol.
14. Pregnancy, lactation, or inadequate contraception. Women must be post-menopausal, infertile, or use a reliable means of contraception. Women of childbearing potential must have a negative pregnancy test done within 7 days prior to registration. Men must have been surgically sterilised or use a (double if required) barrier method of contraception.

COLCHICINE-COG Exclusion criteria:

1. Suspected or established dementia diagnosis (MMSE <23);
2. Intellectual or developmental disability;
3. History of head injury with loss of consciousness >30 minutes;
4. History of major neurological illness (e.g. stroke, epilepsy);
5. History of psychiatric illness (other than affective disorder e.g. schizophrenia, bipolar disorder);
6. History of electroconvulsive therapy or deep brain stimulation;
7. Current/past alcohol or substance dependence (other than nicotine);
8. Any known medical condition which may affect cognition (e.g. cancer, chronic fatigue syndrome); and/or
9. Contraindications to magnetic resonance imaging scanning (e.g. aneurysm clip, pacemaker, etc.).

Study design**Purpose of the study**

Treatment

Allocation to intervention

Randomised controlled trial

Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)

This is a randomised (1:1), placebo-controlled, double-blind multi-centre superiority trial of 3000 patients. We will blind the participants to their intervention. We will also blind the investigators and data collectors (who will see participants at regular follow-up) to whether the participant they are seeing is in the treatment or placebo group. This blinding process will remain intact over the entire course of the study (from allocation to final follow-up after one year post treatment commencement). The method of allocation concealment will be central computerised randomisation.

Methods used to generate the sequence in which subjects will be randomised (sequence generation)

Computer-generated sequence. Randomisation will stratify by statin dose (to prevent confounding effects of the possible anti-inflammatory actions of statins and LDLc achieved), hs-CRP levels, BP, age, sex, anterior vs other MI site and study site.

Masking / blinding

Blinded (masking used)

Who is / are masked / blinded?	The people receiving the treatment/s The people administering the treatment/s The people assessing the outcomes The people analysing the results/data
Intervention assignment	Parallel
Other design features	
Phase	Phase 3
Type of endpoint(s)	Safety/efficacy
Statistical methods / analysis	Our power calculation is based on existing evidence which examined recurrent event rates post ACS in patients. Large trials identified at least a 20% event rate over 3 years in ACS survivors, even when not stratified by hsCRP. Thus, in the control arm of our study, we have assumed a conservative 20% event rate. In statin therapy trials in patients post-ACS, there was a relative risk reduction (RRR) of at least 33% in patients with hsCRP > 2 mg/L. We have taken a conservative RRR of 25%, resulting in an estimated 15% event rate in the treatment arm. Allowing for a 10% loss to follow-up and 10% non-compliance rate, and 90% power, this means we will need to recruit 3000 patients (1500 in each arm) in total. All analyses will use the intention to treat principle. Time to event outcomes will be compared using Kaplan-Meier curves and Cox regression analyses. Continuous outcomes will be assessed for normality and analysed with suitable linear models. COLCHICINE-COG sub-study: Data obtained will guide future studies by providing 95% confidence limits for sensitivity analyses for power calculations of a larger trial if warranted. Data will be analysed using mixed-model analyses of variance in SAS (SAS Institute, Version 9.4) to test whether either of the treatments are different from the other. Treatment will be fixed effects and the patient code will be used as a random effect. Outcomes will be analysed using Linear Mixed Model Analysis of variance due to expected interpatient variability and repeated measures. Treatment will be fixed effects and the patient code will be used as a random effect. The least-squares means procedure will be used in the mixed-model analyses to handle missing data. All participants will be analysed in the groups they have been randomised to as per intention to treat principles. Correlations between outcomes of interest will be examined using Pearson's or Spearman's correlation where appropriate.

Recruitment

Recruitment status	Recruiting		
Date of first participant enrolment			
Anticipated	1/07/2020	Actual	27/01/2022
Date of last participant enrolment			
Anticipated	31/12/2023	Actual	
Date of last data collection			
Anticipated	31/12/2026	Actual	
Sample size			
Target	3000	Accrual to date	12
		Final	
Recruitment in Australia			
Recruitment state(s)	NSW,QLD,WA,VIC		
Recruitment hospital [1]	Royal Prince Alfred Hospital - Camperdown		
Recruitment hospital [2]	Concord Repatriation Hospital - Concord		
Recruitment hospital [3]	Westmead Hospital - Westmead		
Recruitment hospital [4]	Royal North Shore Hospital - St Leonards		
Recruitment hospital [5]	Royal Perth Hospital - Perth		
Recruitment hospital [6]	Blacktown Hospital - Blacktown		
Recruitment hospital [7]	Cairns Base Hospital - Cairns		
Recruitment hospital [8]	Fiona Stanley Hospital - Murdoch		

Recruitment hospital [9]	Gold Coast University Hospital - Southport
Recruitment hospital [10]	Gosford Hospital - Gosford
Recruitment hospital [11]	Liverpool Hospital - Liverpool
Recruitment hospital [12]	Monash Medical Centre - Clayton campus - Clayton
Recruitment hospital [13]	Nepean Hospital - Kingswood
Recruitment hospital [14]	Royal Brisbane & Womens Hospital - Herston
Recruitment hospital [15]	Wollongong Hospital - Wollongong
Recruitment postcode(s) [1]	2050 - Camperdown
Recruitment postcode(s) [2]	2139 - Concord
Recruitment postcode(s) [3]	2145 - Westmead
Recruitment postcode(s) [4]	2065 - St Leonards
Recruitment postcode(s) [5]	6000 - Perth
Recruitment postcode(s) [6]	2148 - Blacktown
Recruitment postcode(s) [7]	4870 - Cairns
Recruitment postcode(s) [8]	6150 - Murdoch
Recruitment postcode(s) [9]	4215 - Southport
Recruitment postcode(s) [10]	2250 - Gosford
Recruitment postcode(s) [11]	2170 - Liverpool
Recruitment postcode(s) [12]	3168 - Clayton
Recruitment postcode(s) [13]	2747 - Kingswood
Recruitment postcode(s) [14]	4029 - Herston
Recruitment postcode(s) [15]	2500 - Wollongong

Recruitment outside Australia

Country [1]	Chile
State/province [1]	Santiago

Funding & Sponsors

Funding source category [1]	Government body
Name [1]	National Health and Medical Research Council (NHMRC)
Address [1]	16 Marcus Clarke Street Canberra ACT 2601
Country [1]	Australia
Funding source category [2]	Charities/Societies/Foundations
Name [2]	National Heart Foundation of Australia
Address [2]	80 William St, Woolloomooloo NSW 2011
Country [2]	Australia
Primary sponsor type	University
Name	University of Sydney
Address	NHMRC CTC Medical Foundation Building Level 6, 92-94 Parramatta Road Camperdown NSW 2050
Country	Australia
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	Sydney Local Health District (RPAH Zone)
Ethics committee address [1]	Research Ethics and Governance Office Royal Prince Alfred Hospital RPAH Medical Centre Suite 210A, 100 Carillon Ave Newtown NSW 2042
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	18/01/2018
Approval date [1]	24/08/2018
Ethics approval number [1]	X18-0004 COLCARDIO-ACS Main study
Ethics committee name [2]	Sydney Local Health District (RPAH Zone)
Ethics committee address [2]	Research Ethics and Governance Office Royal Prince Alfred Hospital RPAH Medical Centre Suite 210A, 100 Carillon Ave Newtown NSW 2042
Ethics committee country [2]	Australia
Date submitted for ethics approval [2]	
Approval date [2]	30/11/2021
Ethics approval number [2]	X20-0057 COLCHICINE-COG Sub-study

Summary

Brief summary	COLCARDIO-ACS Main study: Inflammation plays a pivotal role in atherosclerosis, offering new opportunities for the prevention and treatment of coronary artery disease. Colchicine is a commonly used anti-inflammatory medication approved for the treatment of gout, Familial Mediterranean Fever, and acute/recurrent pericarditis. There is an increasing body of evidence in the medical literature supporting a beneficial role of long term colchicine therapy in prevention of cardiovascular disease, via modulation of inflammatory cytokine production and tubulin-mediated mitosis inhibition. This includes both primary prevention in patients treated with colchicine for gout or Familial Mediterranean Fever, and secondary prevention in patients with stable coronary artery disease who are also being treated with statins and anti-platelet agents. Low-dose colchicine use has also been proven to be safe, well tolerated, and is inexpensive and readily available. The aim of this project is to assess the effect of colchicine (0.5 mg/day) in addition to optimal medical therapy on cardiovascular outcomes in ACS patients with evidence of persistent coronary inflammation (based on hsCRP). We hypothesise that addition of colchicine to optimal medical therapy in patients post-ACS, who have biomarker evidence of persistent inflammation will reduce recurrent cardiovascular events. COLCHICINE-COG Sub-study: Dementia affects over 400,000 Australians at a cost to the economy of \$30 billion per year and is a Commonwealth Government National Health Priority. It is the third leading cause of death overall and the largest reason for disability in older Australians. Cardiovascular disease (CVD) has been identified as the earliest and strongest pathological marker for dementia. Oxidative stress is characterised by an imbalance in the redox state of cells (either via the overproduction of reactive oxygen species of antioxidant system dysfunction) and is posited to be a key mechanistic pathway underpinning the relationship between CVD and cognitive decline. Importantly, research suggests that the pathology leading to dementia occurs 10-20 years before the onset of clinical symptoms. Therefore, it is critical that interventions target CVD in those 'at risk' to prevent onset and reduce cognitive decline. The aim of this study is to examine the effect of long term low-dose colchicine on cognition and brain health patients with established coronary artery disease.
Trial website	None
Trial related presentations / publications	None

Public notes

None

Contacts

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Data sharing statement

Will individual participant data (IPD) for this trial be available (including data dictionaries)? No
No/undecided IPD sharing reason/comment Individual participant data will not be made available; only aggregates/means/statistical summaries.
What supporting documents are/will be available? No other documents available

Summary results

No Results

[< BACK](#)

6/1/23, 1:50 PM

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[Home](#)
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[Useful links](#)
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[Contact](#)
[Privacy](#)
[Terms and conditions](#)

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[Login](#)
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[How to update a trial](#)
[Data item definitions](#)
[Hints and tips](#)
[FAQs](#)

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