



Trial Review

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

Updating a registered trial?

New videos with [general tips for updating](#), and how to [update recruitment status \(Step 7\)](#) are now available!

[VIEW TRIAL AT REGISTRATION](#)

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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](#)

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Trial registered on ANZCTR

Registration number	ACTRN12610000293066
Ethics application status	Approved
Date submitted	8/04/2010
Date registered	13/04/2010
Date last updated	18/02/2014
Type of registration	Retrospectively registered

Titles & IDs

Public title	The LoDoCo Trial: The effect of low dose colchicine on the natural history of patients with stable coronary artery disease
Scientific title	The LoDoCo Trial: The effect of low dose colchicine on the natural history of patients with stable coronary artery disease
Secondary ID [1]	Nil
Universal Trial Number (UTN)	U1111-1114-5895
Trial acronym	LoDoCo Study
Linked study record	

Health condition

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

Coronary artery disease
 Acute ischemic coronary events
 Acute ischemic cerebrovascular events

Condition category

Condition code

Cardiovascular

Coronary heart disease

Stroke

Ischaemic

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	Colchicine 0.5mg/day orally for duration of study period unless side effects occur [minimum of 2 years]
Intervention code [1]	Treatment: Drugs
Comparator / control treatment	No colchicine
Control group	Active

Outcomes

Primary outcome [1]	Composite of: Major Adverse Cardiac or Cerebrovascular Events [MACCE] including [a] Acute coronary syndromes as evidenced by a history of ischemic chest pain, changes in the electrocardiogram and a rise in serum Troponin above the normal range [b] Unstable [new or worsening] angina associated with a documented change in coronary anatomy as evidenced by repeat angiography [c] Sudden Cardiac Death as evidenced by the death certificate or non-fatal out of hospital cardiac arrest [d] New [documented] stroke unrelated to atrial fibrillation or intra-cranial hemorrhage as evidenced by a diagnostic change on cerebral tomography [CT] or magnetic resonant imaging [MRI] of the brain AND after review of the patient and all relevant data by an independent specialist neurologist]
Timepoint [1]	The final analysis will occur once the last patient enrolled to the study has been followed for 2 years.
Secondary outcome [1]	Tolerability to therapy as evidenced by the patients self reporting of side-effects and willingness to continue therapy.
Timepoint [1]	Intolerance will be considered as being 'early' if the patient chooses to cease treatment due to perceived side effect within 1 month of starting treatment, and 'late' if side-effects begin after that time

Eligibility

Key inclusion criteria	Angiographic proof of coronary disease Clinically stable for >6months Coronary Artery Bypass Grafting [CABG] more than 10 years ago or CABG at any time if the patient had subsequently had recurrent angina and angiographic evidence of blocked grafts or progressive native coronary disease requiring intervention with angioplasty Willing to be randomised Likely to be compliant
Minimum age	35 Years
Maximum age	85 Years
Sex	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Any clinically significant co-morbidity Clinical instability within prior 6 months CABG<10 years ago unless intervention has been required Unwilling to enrolle or uncertainty re compliance Already on long-term colchicine for unrelated condition Known sensitivity to colchicine Pregnancy

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)	Patients attending out-patient cardiology clinic are told about the study and asked to enter the trial. If they agree the patients information and signed consent form are forwarded to an independent person who then enters the patients clinical details into the study data bases in a sequential manner. The first column of the data base has a random sequence of '1' or '0' indicating whether the patient will [1] or will not [0] receive therapy.

Hence the treating Cardiologist is blinded to the randomisation sequence at the time the patient is recruited into the study

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

A randomization sequence was generated by computer and held by an independent 3rd party and remained concealed from the referring Cardiologists

Masking / blinding

Blinded (masking used)

Who is / are masked / blinded?

Intervention assignment

Parallel

Other design features

Additional patients will be randomized to replace patients who cease the study drug within 30 days because of intolerance to treatment

Phase

Phase 3

Type of endpoint/s

Safety/efficacy

Statistical methods / analysis

Recruitment

Recruitment status

Completed

Date of first participant enrolment

Anticipated 1/09/2008

Actual 8/09/2008

Date of last participant enrolment

Anticipated

Actual 25/05/2010

Date of last data collection

Anticipated

Actual

Sample size

Target 525

Accrual to date

Final

Recruitment in Australia

Recruitment state(s)

Funding & Sponsors

Funding source category [1]

Self funded/Unfunded

Name [1]

Mark Nidorf

Address [1]

3/140 Mounts Bay Rd
Perth 6000
Western Australia

Country [1]

Australia

Funding source category [2]

Other

Name [2]

Heart Care Western Australia.

Address [2]

3/140 Mounts Bat Rd
Perth
Western Australia

Country [2]

Australia

Funding source category [3]

Hospital

Name [3]

Heart Research Institute of Western Australia

Address [3]

Sir Charles Gairdner Hospital
Verdun St
Nedlands

Country [3]

Australia

Primary sponsor type	Individual
Name	Mark Nidorf
Address	3/140 Mounts Bay Rd Perth 6000 Western Australia
Country	Australia
Secondary sponsor category [1]	Hospital
Name [1]	Heart Research Institute of Western Australia
Address [1]	Queen Elizabeth II Hospital Nedlands Perth 6009 Western Australia
Country [1]	Australia
Secondary sponsor category [2]	Individual
Name [2]	John Eikelboom
Address [2]	Henderson Research Centre McMaster University 711 Concession Street Hamilton, Ontario Canada L8V 1C3
Country [2]	Canada

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	Queen Elizabeth II Hospital
Ethics committee address [1]	Verdun St Nedlands, 6009 Perth Western Australia
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	01/02/2008
Approval date [1]	01/07/2008
Ethics approval number [1]	2008-001

Summary

Brief summary	Prospective Randomized Observer Blinded Evaluation trial to determine the effect of adding colchicine 0.5mg/d to usual medical therapy in patients with proven coronary disease on the risk of future coronary events and stroke [unrelated to atrial fibrillation or intra-cranial hemorrhage]
Trial website	N/A
Public notes	

Contacts

Principal investigator	
Name	Dr Mark Nidorf
Address	Heart Care Western Australia 3/140 Mounts Bay Rd Perth 6000 Western Australia
Country	Australia
Phone	+61413145410

Fax +61 8 93211012
Email smnidorf@gmail.com

Contact person for public queries

Name Dr Mark Nidorf
Address 3/140 Mounts Bay Rd
Perth 6000
Western Australia
Country Australia
Phone +61413145410
Fax +61 8 93211012
Email smnidorf@gmail.com

Contact person for scientific queries

Name Dr Mark Nidorf
Address 3/140 Mounts Bay Rd
Perth 6000
Western Australia
Country Australia
Phone +61413145410
Fax +61 8 93211012
Email smnidorf@gmail.com

No information has been provided regarding IPD availability

Summary results

Have study results been published in a peer-reviewed journal?

Other publications

Have study results been made publicly available in another format?

Results – basic reporting

Results – plain English summary

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