Preventive Angioplasty in Myocardial Infarction Trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/08/2009		[] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
07/10/2009	Completed	[X] Results		
Last Edited 27/09/2013	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Study website http://www.wolfson.qmul.ac.uk/epm/research/prami/index.html

Contact information

Type(s) Scientific

Contact name Dr David Wald

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 07/H0703/109

Study information

Scientific Title

Preventive Angioplasty in Myocardial Infarction Trial: a randomised controlled trial

Acronym

PRAMI

Study objectives

A randomised trial among patients with an acute myocardial infarction (AMI) undergoing a therapeutic angioplasty (a procedure to unblock the artery causing the AMI), to determine the value of preventive angioplasty (additional angioplasty to dilate all other narrowed coronary arteries that were not the cause of the AMI but may cause a future infarct) undertaken as an immediate follow-on procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s) East London and the City Research Ethics Committee approved in December 2007

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

Six hundred patients with AMI will be allocated at random to receive therapeutic angioplasty alone or therapeutic angioplasty plus preventive angioplasty undertaken as an immediate followon procedure. Patients will be followed up for an average of 3 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

All outcomes will be recorded during the period of follow up and analysed 1 year after the last patient is recruited:

- 1. Death
- 2. Non-fatal MI
- 3. Refractory angina

Secondary outcome measures

All outcomes will be recorded during the period of follow up and analysed 1 year after the last patient is recruited:

- 1. Repeat revascularisation
- 2. Complications of angioplasty
- 3. Angina score
- 4. EQ510
- 5. Economic evaluation

Overall study start date

14/04/2008

Completion date

14/04/2012

Eligibility

Key inclusion criteria

Patients (no age limits, either sex) with acute myocardial infarction undergoing a therapeutic angioplasty to the infarct related artery

Participant type(s)

Patient

Age group Other

Sex

Both

Target number of participants 600

Key exclusion criteria

Cardiogenic shock
Coronary artery bypass graft (CABG)

Date of first enrolment 14/04/2008

Date of final enrolment 14/04/2012

Locations

Countries of recruitment England

United Kingdom

Study participating centre Wolfson Institute of Preventive Medicine London United Kingdom EC1M 6BQ

Sponsor information

Organisation Queen Mary University of London (UK)

Sponsor details

Clinical Operations Manager Joint R & D Office Barts and the London Trust/Barts and the London School of Medicine & Dentistry QM Innovation Centre 5 Walden Street London England United Kingdom E1 2EF

Sponsor type University/education

Website http://www.qmul.ac.uk/

ROR https://ror.org/026zzn846

Funder(s)

Funder type Charity

Funder Name Bart's and the London Trust (BLT) Charitable Foundation (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	19/09/2013		Yes	No