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Inflammatory and endothelial markers in heart disease: relation to tissue factor TF - effect of early controlled exercises post acute myocardial infarction on IL6, E-selectin, and TF

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/08/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0158141878

Study information

Scientific Title

Inflammatory and endothelial markers in heart disease: relation to tissue factor TF - effect of early controlled exercises post acute myocardial infarction on IL6, E-selectin, and TF

Study objectives
1. Patients who start high level controlled exercise post acute myocardial infarction (AMI) have lower research indices (IL6, TF, E-selectin) in comparison to those who start low level controlled exercise at the time of their discharge from rehab and at 3 & 6 month post AMI.
2. Patients who perform early controlled exercises post AMI have lower research indices in comparison to late controlled exercise at 3 & 6 month post AMI?
3. Patients with lower levels of research indices at the end of their rehab, 3 & 6 will have better outcome at 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular: Acute myocardial infarction

Interventions
1. Usually Patients who are admitted to CCU/Medical wards with acute myocardial infarction are approached by cardiac rehabilitation nurses to invite them to our cardiac rehabilitation program. Patients information sheet concerning this study will be given to all patient, and later on (pre-discharge from hospital) will be visited by the research Doctor for further discussion, if they are happy to participate in this study a written informed consent will be obtained, and basic clinical information will be recorded on a standard Performa: this will include: Demography, height, weight, BMI, medication, risk factors (smoking status, diabetes, hypercholestraemia, family history, hypertension), any relevant past medical history (MI, CVA, TIA¿etc) will be recorded.

2. Patients undertaking this study will have their blood tested prior discharge from hospital (T0) for the research markers.

3. Patient will do their exercise test within day (5-14) post acute myocardial infarction, and according to their ETT results will divided into 4 groups: Patient who are unable to exercise for any reason will act as a control group. All eligible patients will have Modified Bruce Protocol within 5-14 days post acute myocardial infarction. Patient who have negative exercise test for inducible myocardial ischaemia at moderate/high work load(>7 METS), will be randomised using the above mentioned method. Into 4 groups:
i) Early rehab with high work load exercises.

ii) Late rehab with high work load exercises.
iii) Early rehab with low work load exercises.
vi) Late rehab with low work load exercises.
Blood samples will be collected on attendance for ETT, pre (T1) and post (T2)

4. In addition to our assessment of the above-mentioned marker all groups will be followed for 12 months in term of:
- Mortality (cardiovascular death)
- Morbidity (MI, unstable angina, unstable coronary syndrome, LV failure, re-vascularisation).
Blood samples will be obtained through this sheath (15 mls) will be spun at 3000 rp/m for 15 minutes, and the citrated plasma obtained will be divided into four aliquots, and will be stored at (-40 to -80 o C) and will later be transferred to the Haemostasis Thrombosis and Vascular unit, University of Birmingham for batched analyses by in house ELISA (IL6, Tf, E-selectin).

Intervention Type
Behavioural

Primary outcome(s)
1. Level of IL6/CRP at pre discharge, 1st and last attendance to the gym, 3 & 6 month post myocardial infarction
2. Level of E-selectin at pre discharge, 1st and last attendance to the gym, 3 & 6 month post myocardial infarction
3. Level of TF at pre discharge, 1st and last attendance to the gym, 3 & 6 month post myocardial infarction

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/05/2005

Eligibility

Key inclusion criteria
1. History of recent acute myocardial infarction (within the last 2 weeks)
2. Age 18-80
3. Able to give written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
City General Hospital
Stoke-on-Trent
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium - North Staffordshire Hospital Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration