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The effects of angiotensin 2 blockade and long acting nitrates on arterial stiffness in patients with Marfan Syndrome. A placebo controlled study (NITRATES)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
25/04/2018

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544129339

Study information

Scientific Title
The effects of angiotensin 2 blockade and long acting nitrates on arterial stiffness in patients with Marfan Syndrome. A placebo controlled study (NITRATES)

Study objectives
Angiotensin 2 antagonists and nitrates reduce arterial stiffness in patients with Marfan Syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Marfan syndrome

Interventions
Patients with Marfan Syndrome (MFS) develop dissection of the aorta and aortic valve incompetence which can lead to premature death. Administration of beta adrenoceptor blockers slows aortic dissection and in one study reduced the number of cardiovascular events when compared to placebo. In the light of new trial evidence and some in vitro experimentation it is possible that other classes of drug, the angiotensin 2 antagonist and the nitrates may have a superior benefit to the beta blocker in these patients. We aim to test this hypothesis by administering these drugs in the setting of a clinical trial and measuring the response using detailed arterial stiffness measurements. In this way we hope to compare the nitrate to the

angiotensin 2 antagonist and placebo. This may subsequently form the basis for a larger multi centre trial.
Cross-over design comparing nitrates + angiotensin or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
23/06/2003

Completion date
22/06/2006

Eligibility

Key inclusion criteria
30 subjects aged 18-30

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
23/06/2003

Date of final enrolment
22/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box No 110
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Research organisation

Funder Name
Cambridge Consortium - Addenbrooke's (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