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The effects of angiotensin 2 blockade on arterial stiffness in patients with Marfan Syndrome: a comparison with beta blockade and placebo (BETA BLOCKER)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
20/04/2018

Condition category
Skin and Connective Tissue Diseases

[ ] 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

Contact name
Prof Morris J Brown

Contact details
Queen Mary University of London
Mile End Road
London
United Kingdom
E1 4NS
+44 20 7882 5555
morris.brown@qmul.ac.uk

Additional identifiers

Protocol serial number
N0544125986

Study information

Scientific Title
The effects of angiotensin 2 blockade on arterial stiffness in patients with Marfan Syndrome: a comparison with beta blockade and placebo (BETA BLOCKER)

Study objectives
Do angiotensin 2 antagonists reduce arterial stiffness in patients with Marfan Syndrome when compared to patients taking beta blockade or placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised placebo controlled crossover group trial

Study type(s)
Not Specified

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 dilation 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 a new class of drug, the angiotensin 2 antagonist may have an superior benefit to the beta blocker in these patients. We aim to test this hypothesis by administering this drug in the setting of a clinical trial and measuring the response using detailed arterial stiffness measurements. In this way we hope to compare the beta blocker to the angiotensin 2 antagonist. This may subsequently form the basis for a larger multicentre trial.
Cross-over design comparing beta blocker + angiotensin 2 or placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

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

Completion date

20/03/2006

Eligibility

Key inclusion criteria
30 patients aged 18-30

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
21/03/2003

Date of final enrolment
20/03/2006

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Research organisation

Funder Name
Cambridge Consortium - Addenbrookes (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration