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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 20/04/2018	**Condition category** Skin and Connective Tissue Diseases	

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
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

Study design
Randomised placebo controlled crossover group 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 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
21/03/2003

Completion date
20/03/2006

Eligibility

Key inclusion criteria
30 patients aged 18-30

Participant type(s)
Patient

Age group
Adult

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
21/03/2003

Date of final enrolment
20/03/2006

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 - Addenbrookes (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