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

Recruitment status	Prospectively registered
30/09/2004 No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Other	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Morris J Brown

Contact details

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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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration