

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2018	Condition category Other	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

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 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

22/06/2006

Eligibility

Key inclusion criteria

30 subjects aged 18-30

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Upper age limit

30 years

Sex

All

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

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 - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration