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The effects of irbesartan on aortic dilatation in Marfan's syndrome

Submission date	Recruitment status	[X] Prospectively registered
12/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/12/2019	Other	

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
1

Study information

Scientific Title
A prospective, randomised, placebo-controlled double blind, multicentre study of the effects of irbesartan on aortic dilatation in Marfan's syndrome

Acronym
AIMS

Study objectives
To investigate the effects of irbesartan on aortic dilatation in Marfan's syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK Research Ethics Committee pending approval as of 12/02/2010.

Primary study design
Interventional

Study design
Prospective randomised placebo-controlled double-blind multi-centre trial

Study type(s)
Treatment

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

Interventions
1. Run in Phase: 75 mg open label irbesartan (1 month) - all patients
2. Month 2: 150 mg irbesartan/placebo once daily (o.d.)
3. Months 3 - 48: 300 mg irbesartan/placebo o.d.

The proposed target doses are 300 mg o.d. for patients greater than 50 kg and 150 mg o.d. for patients less than 50 kg. Maximum follow up will be 60 months.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Irbesartan

Primary outcome(s)
Absolute change in aortic root diameter per year measured by echocardiography

Key secondary outcome(s)
1. Change in z score per year - where the z score is calculated on aortic root and body surface area (BSA)
2. Clinical events and requirement for surgery including aortic dissection confirmed on transoesophageal echocardiography (TOE), magnetic resonance imaging (MRI) or computed tomography (CT)

3. Aortic dissection requiring emergency surgery
4. Aortic dissection requiring elective surgery
5. Aortic dilatation requiring elective or emergency surgery
6. Sudden death
7. Cerebrovascular accident
8. Cardiovascular death
9. Aortic regurgitation requiring surgery
10. Death during surgery for any of the above
11. Left ventricular function determined by volumes and ejection fraction
12. Left ventricular mass measurements
13. Assessment of valvular function
14. Cardiac rhythm and voltage
15. Height
16. Arm span and lower segment measurements
17. Fibrillin-1 mutation analysis will be performed in those patients whose mutation status is unknown

All outcomes are measured annually.

Completion date
03/03/2017

Eligibility

Key inclusion criteria
1. Clinically confirmed Marfan's syndrome
2. Aorta dilated above the normal 95th percentile
3. Greater than 6 and less than 40 years of age, either sex
4. Provision of informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
192

Key exclusion criteria
1. Previous cardiac or aortic surgery
2. Planned cardiac or aortic surgery
3. Aortic diameter greater than or equal to 4.5 cm
4. Haemodynamically significant, severe valvular disease

5. Heart failure (defined as left ventricular ejection fraction [LVEF] less than 40%)
6. Therapeutic use of angiotensin converting enzyme (ACE) inhibitors/angiotensin-II receptor antagonist
7. Previous recorded adverse reaction to the trial medication (irbesartan)
8. Female patient who is pregnant, planning pregnancy or not using reliable contraception
9. Impaired renal function

Date of first enrolment
01/09/2010

Date of final enrolment
03/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Brompton and Harefield NHS Foundation Trust
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Royal Brompton and Harefield NHS Foundation Trust (UK)

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Marfan Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/12/2019	16/12/2019	Yes	No
Protocol article	protocol	01/12/2013		Yes	No