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 [] Statistical analysis plan Registration date Overall study status 06/04/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 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.

Study design

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

Primary study design

Interventional

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_bhf, The British Heart Foundation, 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes