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New Transcatheter Aortic Valve Implantation (TAVI) Guidewire

Submission date	Recruitment status	[_] Prospectively registered
13/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2014	Circulatory System	

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
1.1

Study information

Scientific Title
New Transcatheter Aortic Valve Implantation (TAVI) Guidewire: a prospective first-in-man single-centre open-label non-randomised feasibility study

Acronym
TAVI Guidewire

Study objectives
New guidewire design successfully delivers a transcatheter aortic valve (TAV).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ealing and West London Research Ethics Committee, 31/03/2010, ref: 10/H0710/4

Primary study design
Interventional

Study design
Prospective single-centre open-label non-randomised feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aortic stenosis, cardiovascular disease

Interventions
All consenting patients will be allocated to the normal standard of treatment for TAV implantation including the follow-up. The only difference is the used of the new guidewire during implantation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Technical success of the TAVI procedure, measured at end of procedure

Key secondary outcome(s)
Guidewire performance, measured at end of procedure

Completion date
31/05/2011

Eligibility

Key inclusion criteria
1. Patients scheduled for transcatheter aortic valve implantation (TAVI)
2. Male and female, aged 18 - 100 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2010

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. Georges Hospital
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's, University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
NHS Innovations London (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	22/01/2013		Yes	No