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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Technical success of the TAVI procedure, measured at end of procedure

Secondary outcome measures
Guidewire performance, measured at end of procedure

Overall study start date
01/06/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre

St. Georges Hospital
London
United Kingdom
SW17 0QT

Sponsor information

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

Sponsor details
c/o Ira Jakupovic
Joint Research Office
Ground Floor, Hunter Wing
Cranmer Terrace
London
England
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SW17 0RE

Sponsor type
University/education

Website
http://www.sgul.ac.uk/

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
NHS Innovations London (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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