# New Transcatheter Aortic Valve Implantation (TAVI) Guidewire

| Submission date   | Recruitment status No longer recruiting | Prospectively registered       |  |  |
|-------------------|---|--------------------------------|--|--|
| 13/04/2010        |   | ☐ Protocol                     |  |  |
| Registration date | Overall study status Completed          | Statistical analysis plan      |  |  |
| 18/06/2010        |   | [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

#### Contact name

Dr Stephen Brecker

#### Contact details

St. Georges Hospital Blackshaw Road London United Kingdom SW17 0QT

# 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 United Kingdom SW17 ORE

## 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              |