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Mitroflow® vs Perimount® international clinical evaluation

Submission date	Recruitment status	[ ] Prospectively registered
23/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/05/2016	Circulatory System	[ ] Record updated in last year

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
V10603

Study information

Scientific Title
Mitroflow® vs Perimount® international clinical evaluation

Acronym

FLORENCE

Study objectives
Comparison of haemodynamic data (mitroflow® vs perimount® valves)

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted as of 23 November 2007

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aortic stenosis

Interventions
Aortic valve replacement (Mitroflow® vs Perimount® valves)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following haemodynamic data will be assessed at one and six months post implantation:
1. Effective orifice area
2. Mean pressure gradient
3. Peak pressure gradient
4. Degree LV remodelling

Key secondary outcome(s))
Morbidity and mortality. Duration of follow-up: Six months post implantation

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients undergoing Aortic Valve Replacement (AVR) with annulus less than 25 cm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Poor left ventricular function
2. Redo-aortic valve replacement
3. Other associated disorders
4. Aged greater than 70 years

Date of first enrolment
01/01/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
United Kingdom

England

Belgium

Italy

Switzerland

Study participating centre
Department of Cardiothoracic Surgery
Plymouth
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Sponsor information

Organisation
Sorin Biomedica Cardio S.R.L (Italy)

ROR
https://ror.org/01ys7qn31

Funder(s)

Funder type
Industry

Funder Name
Sorin Biomedica Cardio S.R.L (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration