European muLtIcentric Solo International Registry

Published: 10-01-2007
Last updated: 20-05-2024

Evaluation of the morbidity and mortality rate at 3 and 12 month follow-up in patients implanted with Freedom SOLO prosthesis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30401

Source
ToetsingOnline

Brief title
ELISIR

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
heart valve disease

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Biomedica Cardio s.r.l.
Source(s) of monetary or material Support: Sorin Group Nederland BV.

Intervention

Keyword: biological heart valve, Freedom Solo, registry

Outcome measures

Primary outcome

morbidity and mortality at 3 and 12 month follow-up after aortic valve

replacement

Secondary outcome

- NYHA class at 3 and 12 month follow-up after aortic valve replacement;

- echocardiographic parameters (EOA, MPG, PPG) at preoperative time, 3 and 12

months after aortic valve replacement

- Evaluation of suturing time of the Freedom SOLO.

Study description

Background summary

The idea was to create a biological valve which looks similar to your own native aortic valve in a healthy condition.
Freedom Solo represented an innovation in the heart valve prosthesis arena, thanks to its unique characteristics of being a totally biological valve, virtually identical to the native one, which can be easily implanted in a fast way with a single suture line, giving superior results in terms of haemodynamics.

Study objective

Evaluation of the morbidity and mortality rate at 3 and 12 month follow-up in patients implanted with Freedom SOLO prosthesis.

Study design

This is a prospective multicentric European clinical registry.

Study burden and risks

The possible disadvantages and risks of taking part of this study are common to all patients undergoing aortic valve replacement.

It is hoped that replacing the narrowed or leaking aortic valve with a new artificial valve will improve the pumping action of the heart. It is not possible to say if it is better for the patient, but the information we get from this registry may help us decide the best treatment in the future for patients with aortic valve disease.

Contacts

Public
Sorin Biomedica Cardio s.r.l.

Via Crescentino
Saluggia (VC) 13040
Italie
Scientific
Sorin Biomedica Cardio s.r.l.

Via Crescentino
Saluggia (VC) 13040
Italie

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients are male or female 18 years old or older;
* Patients are willing to sign the informed consent;
* Patients which preoperative evaluation indicated the need for native aortic valve replacement;
* A bioprosthesis is the most suitable alternative for replacement of a dysfunctional or diseased native aortic valve according to the current medical practice for valve selection at the centre.

Exclusion criteria

* Patients with severe evolving systemic diseases which could compromise the regular control visits or determine life expectancy minor than the duration of the study;
* Patients with ejection fraction < 30%;
* Patients with collagenophatic autoimmune disease;
* Patients affected by disorder of calcium metabolism;
* Patients with congenital malformation (bicuspid aortic valve);
* Patients with evident coronary ostia and Valsalva sinuses asymmetry;
* Patients currently participating in the study of an investigational drug or device;
* Patients who are drug abusers, alcohol abuser or unable to give informed consent;
* Patients who are HIV positive;
* Patients with active endocarditis;
* Patients required double valve replacement;
* Patients are known to be noncompliant or are unlikely to complete the study;
* Any other case in which SOLO valve is not indicated.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14108.060.06