

# CAVIAAR - Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root

Head :Lansac Emmanuel, Département de Pathologie cardiaque

Di Centa Isabelle, UNITÉ DE RECHERCHE CLINIQUE PARIS NORD GROUPE HOSPITALIER BICHAT CLAUDE BERNARD

Jourdain Cécile, DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE

Last update : 08/08/2014 | Version : 3 | ID : 60156

## General

### Identification

Detailed name	Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root
---------------	---

Sign or acronym	CAVIAAR
-----------------	---------

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accords CNIL, CPP
--	-------------------

### General Aspects

Medical area	Cardiology
--------------	------------

Health determinants	Genetic
---------------------	---------

Keywords	operative mortality, thromboembolic or haemorrhagic stroke, re-operation, placement, ascending aorta, valve endocarditis, Health episodes, valve, death
----------	---

### Scientific investigator(s) (Contact)

Name of the director	Lansac
----------------------	--------

Surname	Emmanuel
---------	----------

Address	75018 PARIS
---------	-------------

Phone	+ 33 (0)6 64 23 38 25
-------	-----------------------

Email	caviaar@orange.fr
-------	-------------------

Unit	Département de Pathologie cardiaque
------	-------------------------------------

Organization	Institut Mutualiste Montsouris
Name of the director	Di Centa
Surname	Isabelle
Address	75018 PARIS
Phone	+ 33 (0)6 08 15 12 92
Email	isabelle.di-centa@wanadoo.fr
Unit	UNITÉ DE RECHERCHE CLINIQUE PARIS NORD GROUPE HOSPITALIER BICHAT CLAUDE BERNARD
Organization	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS
Name of the director	Jourdain
Surname	Cécile
Address	75011 PARIS
Phone	+ 33 (0)1 44 84 17 32
Email	cecile.jourdain@sls.aphp.fr
Unit	DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE DÉLÉGATION REGIONALE À LA RECHERCHE CLINIQUE
Organization	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Public
Details	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS
Governance of the database	
Sponsor(s) or organisation(s) responsible	APHP
Organisation status	Public
Additional contact	

Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	Yes
Details	Performed at group level (clusters)
Additional information regarding sample selection.	Inclusion method: Prospective
Database objective	
Main objective	<p>General objective: to demonstrate in a prospective open and multicentric cohort study that aortic valve sparing for patients with aortic root aneurysms and/or dystrophic aortic insufficiency is associated with a 45% increase of 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without increased mortality or morbidity events when compared to mechanical valve replacement (surgical treatment reference). Morbidity and mortality is defined as the occurrence of at least one of the composite endpoint events: death, re-operation and/or re-hospitalisation for infection, bleeding event, thromboembolic event or heart failure</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> <li>- To evaluate and compare between both patient groups: the rate of immediate post-operation complications associated with a 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without mortality or morbidity events when evaluated on composite criteria, the changes in quality of life during follow-up using a standardised questionnaire, validated by cardiac surgery, modified SF12 Questionnaire</li> <li>- to evaluate the impact of a teaching programme for a new standardised surgical technique on morbidity and mortality from each investigating surgeon's learning curve and on long-term outcomes (programme combining theoretical and video-assisted surgical procedure training on heart anatomy, first patient surgical mentoring)</li> <li>- To set predictive sonographic criteria: the feasibility of valve repair with promising</li> </ul>

immediate and long-term postoperative results from early diagnosis of criteria composite outcome: To evaluate the sensitivity and specificity of ultrasound parameters, notably on the risk of reoperation and valvular complications - To assess the impact of clinical monitoring and imaging on operated patients with aortic root dystrophy in order to propose a post-operative care protocol that meets cost-benefit objectives

#### Inclusion criteria

- over 18 years of age; - aortic root aneurysms without aortic insufficiency or with dystrophic aortic insufficiency regardless of stage (including Marfan and bicuspid diseases), with indications for surgery conformed to American Heart Association or European Society of Cardiology guidelines or dystrophic aortic insufficiency (bicuspid or tricuspid valves) with no aortic root aneurysm with indications for surgery conformed to American Heart Association or European Society of Cardiology; - scheduled valve repair surgery with annuloplasty according to mechanical valve replacement CAVIAAR study protocol; - Signed information letter and informed consent; - covered by social security insurance or access to CMU (beneficiary or assignee).

#### Population type

Age  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

Population covered Sick population

Gender  
Male  
Woman

Geography area National

Detail of the geography area France

#### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY) 05/2007

#### Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	77:- 46 conservations valvulaires- 19 remplacements prothétiques mécaniques- 12 exclusions
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Paraclinical data (detail)	Imaging
Biological data (detail)	Type of peri-operative and enrolment samples taken: full blood count, haemostasis, blood creatinine, INR, APTT and troponins During follow-up: INR if patient is under AVK
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Procedures	
Data collection method	Self-administered questionnaire: Input from paper questionnaire (Manual input) with double data entry Interview: Input from paper questionnaire (Manual input) with double data entry Clinical Examinations: handwritten (Manual input) with double data entry Biological Analysis: handwritten (Manual input) with double data entry
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 20 years
Links to administrative sources	No
Promotion and access	

## Promotion

Link to the document	<a href="http://caviaar.com/de/Home/Presentations/Presentations-2014.html">http://caviaar.com/de/Home/Presentations/Presentations-2014.html</a>
----------------------	---

Link to the document	<a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=CAVIAAR">http://www.ncbi.nlm.nih.gov/pubmed/?term=CAVIAAR</a>
----------------------	---

Description	List of publications in Pubmed
-------------	--------------------------------

## Access

Terms of data access (charter for data provision, format of data, availability delay)	To be decided if data may be used by academic teams To be decided if data may be used by industrial teams
---	--

Access to aggregated data	Access on specific project only
---------------------------	---------------------------------

Access to individual data	Access on specific project only
---------------------------	---------------------------------