

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

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## General

### Identification

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

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

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|--------------------------------------------------------------------------------------------------------------------------|-------------------|
| 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 |
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### Scientific investigator(s) (Contact)

|                      |        |
|----------------------|--------|
| Name of the director | Lansac |
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|                                                      |                                                                                                 |
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| Organization                                         | Institut Mutualiste Montsouris                                                                  |
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| Unit                                                 | UNITÉ DE RECHERCHE CLINIQUE PARIS NORD<br>GROUPE HOSPITALIER BICHAT CLAUDE BERNARD              |
| Organization                                         | ASSISTANCE PUBLIQUE HOPITAUX DE PARIS                                                           |
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| Unit                                                 | DÉLÉGATION REGIONALE À LA RECHERCHE<br>CLINIQUE DÉLÉGATION REGIONALE À LA<br>RECHERCHE CLINIQUE |
| Organization                                         | ASSISTANCE PUBLIQUE HOPITAUX DE PARIS                                                           |
| Collaborations                                       |                                                                                                 |
| Participation in projects,<br>networks and consortia | Yes                                                                                             |
| Funding                                              |                                                                                                 |
| Funding status                                       | Public                                                                                          |
| Details                                              | ASSISTANCE PUBLIQUE HOPITAUX DE PARIS                                                           |
| Governance of the database                           |                                                                                                 |
| Sponsor(s) or organisation(s)<br>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 CAVIAR 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<br>Declarative data<br>Paraclinical data<br>Biological data                                                                                                                                                                                                                                                                      |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration                                                                                                                                                                                                                                                                                               |
| Declarative data (detail)                    | Paper self-questionnaire<br>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<br>Health event/mortality<br>Quality of life/health perception                                                                                                                                                                                                                                                          |
| Procedures                                   |                                                                                                                                                                                                                                                                                                                                                |
| Data collection method                       | Self-administered questionnaire: Input from paper questionnaire (Manual input) with double data entry<br>Interview: Input from paper questionnaire (Manual input) with double data entry<br>Clinical Examinations: handwritten (Manual input) with double data entry<br>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

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|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| 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> |
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| 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> |
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|-------------|--------------------------------|
| 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<br>To be decided if data may be used by industrial teams |
|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|

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