

FRANCE TAVI - Registry for Transcatheter Aortic Bioprosthetic Valve Implantation

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General

Identification

Detailed name Registry for Transcatheter Aortic Bioprosthetic Valve Implantation

Sign or acronym FRANCE TAVI

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL no. 912449 on 20/12/2012.

General Aspects

Medical area Cardiology

Health determinants Iatrogenic

Keywords catheter., Valves

Scientific investigator(s) (Contact)

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Unit Cardiologie Interventionnelle

Organization Hôpital

Collaborations

Funding

Funding status	Private
Details	French Cardiology Society.
Governance of the database	
Sponsor(s) or organisation(s) responsible	Société Française de Cardiologie
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Database objective	
Main objective	<p>Main objective:: To identify all patients undergoing a valve change by transcatheter implantation, who fulfil the selection and technical criteria, that accept the scheduled assessments as part of the disease and who agreed to participate in the study and survival rate assessment at one year.</p> <p>Secondary objectives: To collect epidemiological data on this new technique.</p>
Inclusion criteria	<ul style="list-style-type: none"> - Aged 18 years or over; - Undergoing a valve change by transcatheter implantation; - Individuals that gave clear consent.
Population type	
Age	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Male Woman
Geography area	National

Detail of the geography area	Massy, Caen, Rouen, Brest, Lille, Marseilles, Toulouse, Strasbourg, Saint-Laurent-du-var, Rennes, Le Chesnay, Nantes, Saint-Denis, Paris, Caluire-et-cuire, Angers, Clermont-Ferrand, Tours, Montpellier, Villeurbanne, Bron, Bois-Bernard, Amiens, Montpellier, Bordeaux, Dijon, Grenoble, Poitiers, Pessac, Metz, Le Plessis-Robinson, Mulhouse, Vandoeuvre-Lesnancy and Saint-Etienne.
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	02/2013
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Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
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Details of the number of individuals	4,016 patients enrolled in 47 centres on 03/06/2014.
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Paraclinical data
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Clinical data (detail)	Medical registration
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Details of collected clinical data	Functional status, medical history, background, pre-implantation assessment, implantation procedure, hospital discharge, complications, vital status, treatment.
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Paraclinical data (detail)	Ultrasound.
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality
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Procedures

Participant monitoring	Yes
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Details on monitoring of participants	Follow-up at one month then every year.
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Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://tinyurl.com/PUBMED-FRANCETAVI
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Description	Liste des publications dans Pubmed
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Access

Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
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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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