

REFLEX - Longitudinal Study on Aortic Regurgitation in Patients Treated with Benfluorex

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:- Épidémiologie respiratoire: de l'étiologie de l'asthme et de la BPCO au pronostic de la transplantation
pulmonaire

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General	
Identification	
Detailed name	Longitudinal Study on Aortic Regurgitation in Patients Treated with Benfluorex
Sign or acronym	REFLEX
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL no. 1286925
General Aspects	
Medical area	Cardiology
Health determinants	Medicine
Keywords	Benfluorex, marketing authorisation, MA, research, side effects, post, adverse events, study
Scientific investigator(s) (Contact)	
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Organization	Institut national de la santé et de la recherche médicale -
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Collaborations

Funding

Funding status	Public
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Details	Ministry of Health.
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Governance of the database

Sponsor(s) or organisation(s) responsible	Institut national de la santé et de la recherche médicale - Inserm
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Organisation status	Public
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Longitudinal study (except cohorts)
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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Additional information regarding sample selection.	Patients that meet the inclusion criteria are consecutively and systematically enrolled for one year.
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Database objective

Main objective	Echocardiography-based study on the development of valvular disease (decrease, stable, increase) in patients treated with benfluorex.
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	To compare the development of valvular diseases potentially linked to benfluorex and diseases not linked to benfluorex. - All patients and patients with valvular disease
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potentially linked to benfluorex; assessment of development with regards to:

- Indication(s), duration of exposure to benfluorex and duration since stopping medication.
- Age and sex;
- diabetes and associated medical treatment.
- Presence of cardiac and non-cardiac diseases;
- current treatments and treatments that were undergone simultaneously with benfluorex.

Inclusion criteria

- Male and female;
- Adult;
- Patient treated with benfluorex from 2006-2009 with aortic/mitral grade regurgitation.

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)

Population covered

Sick population

Gender

Male
Woman

Geography area

National

Detail of the geography area

60 cardiology centres throughout France.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2011

Size of the database

Size of the database (number of individuals)

[500-1000[individuals

Details of the number of individuals

1,000

Data

Database activity

Current data collection

Type of data collected

Clinical data
Paraclinical data

Clinical data (detail)

Direct physical measures

Details of collected clinical data	---
Paraclinical data (detail)	Echocardiography.
Presence of a biobank	No
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	Clinical and echocardiography data will be recorded at enrolment and follow-up visits.
Participant monitoring	Yes
Details on monitoring of participants	Additional visits will be provided if necessary, as part of regular patient monitoring.
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only