

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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Unit U1152 Physiopathologie et épidémiologie des maladies respiratoiresÉquipe/activité :-
Épidémiologie respiratoire: de l'étiologie de l'asthme et de la BPCO au pronostic de la transplantation pulmonaire

Organization

Institut national de la santé et de la recherche
médicale -

Collaborations

Funding

Funding status

Public

Details

Ministry of Health.

Governance of the database

Sponsor(s) or organisation(s)
responsible

Institut national de la santé et de la recherche
médicale - Inserm

Organisation status

Public

Additional contact

Main features

Type of database

Type of database

Study databases

Study databases (details)

Longitudinal study (except cohorts)

Database recruitment is carried
out by an intermediary

A selection of health institutions and services

Database recruitment is made
on the basis of:

Medication(s) taken

Database recruitment is carried
out as part of an interventional
study

No

Additional information regarding
sample selection.

Patients that meet the inclusion criteria are
consecutively and systematically enrolled for one
year.

Database objective

Main objective

Echocardiography-based study on the development
of valvular disease (decrease, stable, increase) in
patients treated with benfluorex.

To compare the development of valvular diseases
potentially linked to benfluorex and diseases not
linked to benfluorex.

- All patients and patients with valvular disease

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