

SISTOLA - Observational usage and effectiveness of candesartan in heart failure treatment in France

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General	
Identification	
Detailed name	Observational usage and effectiveness of candesartan in heart failure treatment in France
Sign or acronym	SISTOLA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL approval : 907230 - 27 November 2007
General Aspects	
Medical area	Cardiology
Others (details)	Congestive heart failure
Keywords	candesartan
Scientific investigator(s) (Contact)	
Name of the director	Thomas-Delcourt
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Unit	AstraZeneca
Collaborations	
Funding	
Funding status	Private
Details	AstraZeneca / Takeda
Governance of the database	

Sponsor(s) or organisation(s) responsible	ASTRAZENECA / TAKEDA
Organisation status	Private
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
Database objective	
Main objective	To describe the way candesartan is used in heart failure treatment in France (treatment initiation and follow-up) treatment discontinuation occurrences and reasons why and patients clinical evolution
Inclusion criteria	Patients starting or who have recently started (less than 30 days) a treatment with candesartan for heart failure
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	Consultation in cardiology

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2008

Date of last collection (YYYY or MM/YYYY) 2010

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 452

Data

Database activity Data collection completed

Type of data collected
Clinical data
Declarative data
Biological data

Clinical data (detail)
Direct physical measures
Medical registration

Declarative data (detail)
Phone interview

Biological data (detail)
ionogram, with blood potassium in particular, natremia and kidney function

Presence of a biobank No

Health parameters studied
Health event/morbidity
Health event/mortality

Procedures

Participant monitoring Yes

Details on monitoring of participants 12 months

Links to administrative sources No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)

Methods for accessing the database are currently being defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only