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

Head :Thomas-Delcourt Florence, AstraZeneca

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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
Surname	Florence
Phone	+33 (1) 41 29 40 25
Email	florence.thomas@astrazeneca.com
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 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 occurences 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