AVANCE - Observational study of the real-world usage, efficacy and safety of rosiglitazone in Type 2 diabetics

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General

Identification

Detailed name	Observational study of the real-world usage, efficacy and safety of rosiglitazone in Type 2 diabetics
Sign or acronym	AVANCE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS : 05.309

General Aspects

Medical area	Endocrinology and metabolism
Keywords	pharmaco-epidémiologY, rosiglitazone

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	Laboratoire GSK

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
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 care professionals
Database recruitment is 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.	Physicians are to be randomly selected from the CEGEDIM data base. To take stock of refusals, a pool will be constituted containing three times as many specialists and general practitioners as will eventually be required. Every physician in each pool (specialists and general practitioners) will be randomly attributed a number. Lists will then be compiled in ascending order, using this random number. Physicians will then be successively solicited in the order of appearance of their names on the list until the required number of general practitioners or specialists has been attained. The planned inclusion period is nine months. This duration could nevertheless be extended if there are recruitment problems, or curtailed if enough patients have been recruited. During this period, all the Investigating Physicians will be asked to include all patients they see (in consultations or home visits) who start or have recently started (within the previous 30 days) a course of rosiglitazone treatment and who have agreed to take part in the Study, until a maximum number of patients has been reached, namely 4 for the general practitioners and 5 for the specialists. Participating physicians will also be asked to fill out a non-inclusion record for every patient who was in theory eligible but was not included (with the reason for non-inclusion).

Database objective	
Main objective	To describe the profiles of patients being treated by general practitioners and specialists, compatibility of practice with the SPC, patient compliance, and the safety and efficacy of rosiglitazone in "real-world" conditions of use.
Inclusion criteria	- Type 2 diabetic spontaneously consulting (i.e. independently of the study); - Patient who is starting or has recently started (within a month) a course of treatment with Avandia® or Avandamet®; - Patient who has given his/her consent to participate.
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	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1120
Data	

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	CRF and self administrated questionnaire
Participant monitoring	Yes
Details on monitoring of participants	Data will be collected at 5 stages : ? At inclusion ? After about 6 months (Follow-Up Visit 1):Up Visit 3) ? After about 12 months (Follow-Up Visit 2) ? After about 18 months (Follow-Up Visit 3) ? After about 24 months (End-of-Study Visit)
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publication in congress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only