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

Responsable(s) :Leclerc-Zwirn Christel, Laboratoire GSK

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Général

Identification

Nom détaillé	Observational study of the real-world usage, efficacy and safety of rosiglitazone in Type 2 diabetics
Sigle ou acronyme	AVANCE
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CCTIRS : 05.309

Thématiques générales

Domaine médical	Endocrinology and metabolism
Mots-clés	pharmaco-epidémiologY, rosiglitazone

Responsable(s) scientifique(s)

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Laboratoire	Laboratoire GSK

Collaborations

Financements

Financements	Private
Précisions	Laboratoire GSK

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	Laboratoire GSK

Statut de l'organisation	Secteur Privé
Contact(s) supplémentaire(s)	
Caractéristiques	
Type de base de données	
Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Longitudinal study (except cohorts)
Origine du recrutement des participants	A selection of health care professionals
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	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).

Objectif de la base de données	
Objectif principal	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.
Critères d'inclusion	- 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.
Type de population	
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 concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	France
Collecte	
Dates	
Année du premier recueil	2006
Année du dernier recueil	2009
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	[1000-10 000[individuals
Détail du nombre d'individus	1120
Données	
Activité de la base	Data collection completed

Type de données recueillies	Clinical data Declarative data
Données cliniques, précisions	Direct physical measures Medical registration
Données déclaratives, précisions	Paper self-questionnaire Face to face interview
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Medicines consumption
Modalités	
Mode de recueil des données	CRF and self administrated questionnaire
Suivi des participants	Yes
Détail du suivi	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)
Appariement avec des sources administratives	No
Valorisation et accès	
Valorisation et accès	
Accès	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Publication in congress
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only