CHADIG - Profile of patients with type 2 diabetes newly treated with GLP1 analogues in France and Spain

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General

Identification

Detailed name	Profile of patients with type 2 diabetes newly treated with GLP1 analogues in France and Spain
Sign or acronym	CHADIG
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	DR-2013-268

General Aspects

Medical area	Endocrinology and metabolism
Health determinants	Medicine
Keywords	type 2 diabetes, GLP1, renally impaired population, France

Scientific investigator(s) (Contact)

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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)	Not-repeated cross-sectional studies (except case control studies)
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.	The selected practitioners will complete a questionnaire for the first 5 patients (on average) with type 2 diabetes that are prescribed for the first time a GLP1 analogue at a visit during the study period (three months). Patients with a visit during the study period who recently initiated GLP1 analogue therapy (within 3 months prior to the visit) would be also enrolled in the survey if clinical data at initiation of the GLP1 treatment are available.
Database objective	
Main objective	describe the clinical characteristics of a representative cohort of patients with T2DM newly treated with GLP-1 analogues in France & Spain
Inclusion criteria	adult ? 18 years, patient who accept to participate and who are able to read/understand the consent form and provide informed consent and who are not simultaneously participating in a study that included an investigational drug or procedure.

	Patients with a visit during the study period who recently initiated GLP1 analogue therapy (within 3 months prior to the visit) would be also enrolled in the survey if clinical data at initiation of the GLP1 treatment are available
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	International
Detail of the geography area	France &Spain
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	07/2013
Date of last collection (YYYY or MM/YYYY)	12/2013
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	800 :- 400 (France)- 400 (Espagne)
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration

Details of collected clinical data	clinical dossier, medical exam
Declarative data (detail)	Face to face interview
Details of collected declarative data	clinical dossier, medical exam
Biological data (detail)	HbA1c, lipid profile (total cholesterol, LDL, HDL, triglycerides), creatinine
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	e-CRF
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only