CHOICE - CHOICE: CHanges to treatment and Outcomes in patients with type 2 diabetes initiating InjeCtablE therapy

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General

Identification

Detailed name	CHOICE: CHanges to treatment and Outcomes in patients with type 2 diabetes initiating InjeCtablE therapy
Sign or acronym	CHOICE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°908226

General Aspects

Medical area	Endocrinology and metabolism
Keywords	Type-2 diabetes, insulin, exenatide, undesirable effects, HbA1c, quality of life

Scientific investigator(s) (Contact)

Name of the director	Laboratoire
Email	fr_mail_pharmacoepi@lilly.com
Unit	Eli Lilly France

Collaborations

Funding

Funding status	Private
Details	Eli Lilly and Company

Governance of the database

Sponsor(s) or organisation(s) responsible	Eli Lilly

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 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
Additional information regarding sample selection.	Diabetologists and general practitioners. Random selection of practitioners using files.Patients initiating a treatment via insulin or exenatide

Database objective

Main objective	The primary objective of this study is to estimate the time spent on initial treatment regime before significant treatment change for patients with type 2 diabetes initiating therapy with either insulin or exenatide for the first time.
Inclusion criteria	- Adults 18 years and older, - Type-2 diabetes patients who have never received insulin or exenatide and who are initiating a treatment via exenatide or insulin therapy, within the normal routine course of care.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	International

Detail of the geography area	France, Deutschland, Sweden, Denmark, Belgium and Greece
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2388 (1114 exenatide, 1274 insulin)
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Biological data (detail)	HbA1c, glycemia, lipid profile, renal function (if available)
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Data collection notebook and questionnaires
Participant monitoring	Yes

Details on monitoring of participants	2 years follow-up
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Hal-CHOICE
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-CHOICE
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	Reports and publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only