

HYPOCRAS - Cohort of Elderly Patients with T2D. Comparing the Risk of Hypoglycaemia in DPP4-Inhibitors (iDPP4) with Conventional Oral Antidiabetic Drugs as Add-On Therapy to Metformin.

Head :Dejager Sylvie, Biostatistics and Clinical Research Departments

Penfornis Alfred, EA 3920

Bourdel-Marchasson Isabelle

Last update : 06/20/2016 | Version : 1 | ID : 73265

General

Identification

Detailed name	Cohort of Elderly Patients with T2D. Comparing the Risk of Hypoglycaemia in DPP4-Inhibitors (iDPP4) with Conventional Oral Antidiabetic Drugs as Add-On Therapy to Metformin.
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Sign or acronym	HYPOCRAS
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL
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General Aspects

Medical area	Endocrinology and metabolism
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Pathology (details)	Type 2 diabetes
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Health determinants	Healthcare system and access to health care services Iatrogenic Nutrition
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Keywords	type 2 diabetes; elderly subject; DPP4 inhibitors; oral antidiabetic drugs; hypoglycaemia
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Scientific investigator(s) (Contact)

Name of the director	Dejager
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Surname	Sylvie
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Email	sylvie.dejager@psl.aphp.fr
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Unit	Biostatistics and Clinical Research Departments
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Organization	Novartis Pharma
Name of the director	Penfornis
Surname	Alfred
Phone	+33 (0)3 81 66 82 29
Email	alfred.penfornis@ufc-chu.univ-fcomte.fr
Unit	EA 3920
Organization	Jean-Minjoz Hospital
Name of the director	Bourdel-Marchasson
Surname	Isabelle
Email	Isabelle.bourdel-marchasson@chu-bordeaux.fr
Organization	Bordeaux University Hospital
Collaborations	
Funding	
Funding status	Private
Details	Novartis Pharma
Governance of the database	
Sponsor(s) or organisation(s) responsible	Novartis Pharma
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Jean-Minjoz Hospital, Bordeaux University Hospital
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study

Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment 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.	Two cohorts were formed based on two prescribed drugs (either DPP4-i or another oral antidiabetic drug).

Database objective

Main objective	HYPOCRAS aims to compare hypoglycaemic risk in dipeptidyl peptidase-4 inhibitors (iDPP4s) with other oral antidiabetic drugs (OAD) along with metformin in the real-life treatment of elderly patients with type 2 diabetes (T2D).
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Inclusion criteria	Patients eligible for the study were men and women of 65 years of age or over with T2D and HbA1c: $\geq 6.5\%$ after a course of at least 3 months of metformin alone at a stable, maximum tolerated daily dose, requiring the prescription of a second OAD. Patients who had at least two follow-up visits planned over the next 6 months (± 1 month, 3 months, 6 months ± 1 month).
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Population type

Age	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)	2009
Date of last collection (YYYY or MM/YYYY)	2011

MM/YYYY)

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of individuals 1,317

Data

Database activity Data collection completed

Type of data collected Clinical data

Clinical data (detail) Direct physical measures
Medical registration

Details of collected clinical data Details of disease, treatment, hypoglycaemic episodes and glycated haemoglobin (HbA1c) level. Fasting plasma glucose (FPG). Weight fluctuation and patient satisfaction with regards to treatment.

Presence of a biobank No

Health parameters studied Health care consumption and services

Care consumption (detail) Medicines consumption

Procedures

Data collection method By general practitioners

Participant monitoring Yes

Monitoring procedures Monitoring by contact with the referring doctor

Details on monitoring of participants 6-month follow-up with interim visit at 3 months.

Links to administrative sources No

Promotion and access

Promotion

Link to the document <http://www.diabet-metabolism.com/article/S1262-3636%2812%2971192-8/abstract>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/22996038>

Access

Terms of data access (charter for data provision, format of data, availability delay)

Contact the scientist in charge.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only