

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
Penformis 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.

Sign or acronym HYPOCRAS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

CNIL

General Aspects

Medical area Endocrinology and metabolism

Pathology (details) Type 2 diabetes

Health determinants Healthcare system and access to health care services
Iatrogenic
Nutrition

Keywords type 2 diabetes; elderly subject; DPP4 inhibitors; oral antidiabetic drugs; hypoglycaemia

Scientific investigator(s) (Contact)

Name of the director Dejager

Surname Sylvie

Email sylvie.dejager@psl.aphp.fr

Unit Biostatistics and Clinical Research Departments

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).

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 (\pm 1 month, 3 months, 6 months \pm 1 month).

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