

INTENSIVE - Intensification of insulin therapy used in type-2 diabetes patients treated by the association of oral diabetes medication and basal insulin

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General	
Identification	
Detailed name	Intensification of insulin therapy used in type-2 diabetes patients treated by the association of oral diabetes medication and basal insulin
Sign or acronym	INTENSIVE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1250160
General Aspects	
Medical area	Endocrinology and metabolism
Others (details)	type-2 diabetes
Keywords	intensification of insulin therapy
Scientific investigator(s) (Contact)	
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Unit	Sanofi Aventis
Collaborations	
Funding	
Funding status	Private
Details	sanofi-aventis

Governance of the database

Sponsor(s) or organisation(s) responsible Sanofi-aventis France

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 institutions and services

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective Describe the evolution of HbA1c at 6 months under different therapeutic strategies for the intensification of insulin therapy used in type-2 diabetes patients treated by the association of oral diabetes medication and basal insulin requiring the adding of rapid insulin

Inclusion criteria man or woman, over the age of 18 years, having type-2 diabetes meeting the criteria of the HAS: treated by the association of oral diabetes medication and basal insulin (semi slow or slow-acting) and requiring the adding of rapid insulin.

Population type

Age Adulthood (45 to 64 years)
Elderly (65 to 79 years)

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)	2008
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Date of last collection (YYYY or MM/YYYY)	2009
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	389
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Biological data
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Clinical data (detail)	Direct physical measures
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Biological data (detail)	HbA1c; GAJ
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity
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Procedures

Data collection method	type-2 diabetes, intensification of insulin therapy
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Participant monitoring	No
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Links to administrative sources	No
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Promotion and access

Promotion

Access

Terms of data access (charter	commented SFD poster. methods for accessing the
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for data provision, format of data, availability delay)

database are currently being defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only