

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
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	389
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures
Biological data (detail)	HbA1c; GAJ
Presence of a biobank	No
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	type-2 diabetes, intensification of insulin therapy
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter	commented SFD poster. methods for accessing the

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