

Episurvey Hepatite B - A cross-sectional, multicentre, epidemiological study of the drug management in hepatitis B

Head :Bregman Bruno, Bristol-Myers Squibb
Schmidely Nathalie, Bristol-Myers Squibb

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General

Identification

Detailed name A cross-sectional, multicentre, epidemiological study of the drug management in hepatitis B

Sign or acronym Episurvey Hepatite B

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL 833542 version 9

General Aspects

Medical area Infectious diseases

Others (details) hepatitis B

Keywords Chronic hepatitis B, epidemiology, treatment

Scientific investigator(s) (Contact)

Name of the director Bregman

Surname Bruno

Address 3, rue J. Monnier - 92500 Rueil Malmaison

Phone +33 (0)1 58 83 60 00

Email bruno.bregman@bms.com

Unit Bristol-Myers Squibb

Name of the director Schmidely

Surname Nathalie

Address 3, rue J. Monnier - 92500 Rueil Malmaison

Phone	+33 (0)1 58 83 60 00
Email	nathalie.schmidely@bms.com
Unit	Bristol-Myers Squibb
Collaborations	
Funding	
Funding status	Private
Details	Bristol-Myers Squibb
Governance of the database	
Sponsor(s) or organisation(s) responsible	Bristol-Myers Squibb France (BMS)
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 carried out as part of an interventional study	No
Additional information regarding sample selection.	Random sampling in clusters
Database objective	
Main objective	Describe the drug management of patients having chronic hepatitis B, in France, in 2006.
Inclusion criteria	M/F ≥ 18 years, infected by the hepatitis B virus for at least 6 months, seen in outpatient clinic visit at expert centers for caring of hepatitis (Hepatitis Referenced University Hospitals, General Hospital Centres, community-based hepato-

gastroenterologists) between 1 Jan. and 31 March 2006.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population covered	General population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	Metropolitan France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
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Date of last collection (YYYY or MM/YYYY)	2006
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Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
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Details of the number of individuals	1800
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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)	ALT, HBe status, viral load
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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	Case report form
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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 for data provision, format of data, availability delay)	Publications
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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