

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

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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)

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Unit	Bristol-Myers Squibb

Collaborations

Funding

Funding status	Private
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Details	Bristol-Myers Squibb
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Governance of the database

Sponsor(s) or organisation(s) responsible	Bristol-Myers Squibb France (BMS)
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Organisation status	Private
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is carried out as part of an interventional study	No
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Additional information regarding sample selection.	Random sampling in clusters
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Database objective

Main objective	Describe the drug management of patients having chronic hepatitis B, in France, in 2006.
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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-
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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)

Population covered General population

Gender Male
 Woman

Geography area National

Detail of the geography area Metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2006

Date of last collection (YYYY or MM/YYYY) 2006

Size of the database

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

Details of the number of individuals 1800

Data

Database activity Data collection completed

Type of data collected Clinical data
 Biological data

Clinical data (detail) Direct physical measures

Biological data (detail) ALT, HBe status, viral load

Presence of a biobank No

Health parameters studied Health event/morbidity

Procedures

Data collection method Case report form

Participant monitoring No

Links to administrative sources No

Promotion and access

Promotion

Access

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

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only