

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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|--|---|
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| 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) |
|-----|---|

| | |
|--------------------|--------------------|
| 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 |
|--------------------------|-----------------------------|

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|-----------------------|----|
| Presence of a biobank | No |
|-----------------------|----|

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|---------------------------|------------------------|
| Health parameters studied | Health event/morbidity |
|---------------------------|------------------------|

Procedures

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|------------------------|------------------|
| Data collection method | Case report form |
|------------------------|------------------|

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|------------------------|----|
| Participant monitoring | No |
|------------------------|----|

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|---------------------------------|----|
| Links to administrative sources | No |
|---------------------------------|----|

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 |
|---------------------------|---------------------------------|