

CARDIORENAL - Longitudinal observational study on cardiovascular and renal risk in patients with hypertension and at high CV risk

Head :Herrmann Marie-Annick, Bristol-Myers Squibb
Schmidely Nathalie, Bristol-Myers Squibb

Last update : 09/05/2017 | Version : 1 | ID : 130

| General | |
|--|---|
| Identification | |
| Detailed name | Longitudinal observational study on cardiovascular and renal risk in patients with hypertension and at high CV risk |
| Sign or acronym | CARDIORENAL |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL N°903103 |
| General Aspects | |
| Medical area | Cardiology Neurology Urology, andrology and nephrology |
| Health determinants | Genetic Social and psychosocial factors |
| Others (details) | Myocardial infarction, stroke, cardiovascular death |
| Keywords | High-risk patients, cardiovascular event, monitoring |
| Scientific investigator(s) (Contact) | |
| Name of the director | Herrmann |
| Surname | Marie-Annick |
| Address | 3 RUE JOSEPH MONIER 92500 RUEIL-MALMAISON |
| Phone | +33 (1) 58 83 60 00 |
| Email | marie-annick.herrmann@bms.com |
| Unit | Bristol-Myers Squibb |

| | |
|--|---|
| Name of the director | Schmidely |
| Surname | Nathalie |
| Address | 3 RUE JOSEPH MONIER 92500 RUEIL-MALMAISON |
| Phone | +33 (1) 58 83 60 00 |
| Email | nathalie.schmidely@bms.com |
| Unit | Bristol-Myers Squibb |
| Collaborations | |
| Funding | |
| Funding status | Private |
| Details | Bristol-Myers Squibb France / Sanofi-Aventis France |
| Governance of the database | |
| Sponsor(s) or organisation(s) responsible | Bristol-Myers Squibb France (BMS) |
| Organisation status | Private |
| Sponsor(s) or organisation(s) responsible | Sanofi Aventis |
| Organisation status | Private |
| Additional contact | |
| Main features | |
| Type of database | |
| Type of database | Study databases |
| Study databases (details) | Cohort study |
| 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 | Evaluate, over a cohort of patients with a high cardiovascular risk according to the ANAES definition and monitored by a general practitioner, the incidence of the major cardiovascular event (MI, CVA and cardiovascular death) according to the various sub-classes of risks defined by ANAES in the "high risk" level |
| Inclusion criteria | M/F ≥ 18 years, examined in ambulatory consultation by general practitioners and cardiologists, having a treated essential HBP, or such that SBP/DBP $> 140/90$ mmHg in the absence of treatment, monitored in a normal manner by the investigating doctor |
| 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 | Sick 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) | 2003 |
| Date of last collection (YYYY or MM/YYYY) | 2007 |
| Size of the database | |
| Size of the database (number of individuals) | [10 000-20 000[individuals |
| Details of the number of individuals | 16600 |
| Data | |

| | |
|---|--|
| Database activity | Data collection completed |
| Type of data collected | Clinical data |
| Clinical data (detail) | Direct physical measures |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality Health care consumption and services |
| Care consumption (detail) | Hospitalization Medical/paramedical consultation Medicines consumption |
| Procedures | |
| Data collection method | Paper observation notebook |
| Participant monitoring | Yes |
| Details on monitoring of participants | Y1, Y2, Y3 |
| 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 |