

OPISEP - Profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment

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General

Identification

Detailed name Profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment

Sign or acronym OPISEP

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Numéro CNIL 908245, CPP = NA, AFSSAPS = NA

General Aspects

Medical area Neurology

Others (details) multiple sclerosis MS-RR (Relapsing - Remitting)

Keywords central nervous system, first attack under IMD treatment

Scientific investigator(s) (Contact)

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Unit Sanofi Aventis

Collaborations

Funding

Funding status Private

| | |
|--|---|
| Details | Sanofi-aventis France |
| 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) | Longitudinal study (except cohorts) |
| 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 |
| Database objective | |
| Main objective | Describe the profiles of patients suffering from MS-RR according to the delay of appearance of the first attack after initiation the first immunomodulator treatment. |
| Inclusion criteria | ? Patient of legal age (? 18 years) ? Patient suffering from MS-RR ? Patient having, after initiation the first immunomodulator treatment, a recent first attack (less than 10 days) ? Patient accepting to participate in the survey Criteria for non-inclusion ? Patient participating in clinical research (pre-market authorization) |
| 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 | France |
| Data collection | |
| Dates | |
| Date of first collection (YYYY or MM/YYYY) | 2008 |
| Date of last collection (YYYY or MM/YYYY) | 2011 |
| Size of the database | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | Less than 500 individuals |
| Data | |
| Database activity | Current data collection |
| Type of data collected | Clinical data Declarative data Paraclinical data Biological data |
| Clinical data (detail) | Direct physical measures |
| Declarative data (detail) | Face to face interview |
| Paraclinical data (detail) | MRI |
| Biological data (detail) | Search for IFN neutralizing antibodies |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality Health care consumption and services Others |
| Care consumption (detail) | Hospitalization Medical/paramedical consultation Medicines consumption |

| Other (detail) | EDSS scale |
|---|--|
| Procedures | |
| 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) | methods for accessing the database are currently being defined |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |