# - Case-control study on Torsades de pointes (TdP)

Head :Grimaldi-Bensouda Lamiae

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## General

### Identification

| | |
|---|---|
| Detailed name | Case-control study on Torsades de pointes (TdP) |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | 908.026 |

### General Aspects

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|---|---|
| Medical area | Cardiology |
| Others (details) | Torsades de pointes and syncope in long QT syndrome |
| Keywords | Pharmacoepidemiology |

### Scientific investigator(s) (Contact)

| | |
|---|---|
| Name of the director | Grimaldi-Bensouda |
| Surname | Lamiae |
| Address | 10 place de Catalogne - 75014 Paris |
| Phone | + 33 (0)1 55 42 53 00 |
| Email | contact@la-ser.com |

### Collaborations

### Funding

| | |
|---|---|
| Funding status | Mixed |
| Details | LA-SER |

### Governance of the database

| | |
|---|---|
| Sponsor(s) or organisation(s) responsible | LA-SER |

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|---|---|
| Organisation status | Private |
| **Additional contact** | |
| **Main features** | |
| **Type of database** | |
| Type of database | Study databases |
| Study databases (details) | Case control 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. | TdP cases are recruited by a network of rhythmology and cardiology centres and by referrals from a network of general practitioners located throughout the territory. |
| **Database objective** | |
| Main objective | Surveillance and assessment of the risk of torsades de pointes or syncope in long QT syndrome from drug exposure during actual treatment. |
| Inclusion criteria | Case study: patients, men and women aged between 18 and 79, who have experienced a syncopal episode and a torsades de pointes or QT interval higher or equal to 500 ms, declared by a cardiologist, and occurring 30 days before enrolment. |
| **Population type** | |
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years) |
| Population covered | General population |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | France |

| Data collection | |
|---|---|
| **Dates** | |
| Date of first collection (YYYY or MM/YYYY) | 2008 |
| **Size of the database** | |
| Size of the database (number of individuals) | [10 000-20 000[ individuals |
| Details of the number of individuals | 20 cases 13000+ témoins/controls |
| **Data** | |
| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data |
| Clinical data (detail) | Direct physical measures |
| Declarative data (detail) | Phone interview |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity |
| **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) | In progress |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |