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

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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

Medical area Cardiology

Others (details) Torsades de pointes and syncope in long QT

syndrome

Keywords Pharmacoepidemiology

Scientific investigator(s)

(Contact)

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Collaborations

Funding

Funding status Mixed

Details LA-SER

Governance of the database

Sponsor(s) or organisation(s)

responsible

LA-SER

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) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)			
Population covered	General 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			
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 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			