Drugs as risk factors of unexplained sudden cardiac death (SCD). A case-control study

First published: 21/10/2014

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Study Planned

Administrative details

EU PAS number

EUPAS7718

Study ID

7719

DARWIN EU® study

No

Study countries

☐ Spain

Study description

The main objective of the study is to determine the risk of unexplained sudden cardiac death (SCD) associated with proarrhythmic drug use. Secondary objectives are 1) to describe and to compare with controls the main

characteristics (demographic and clinical) of patients with unexplained SCD, 2) to estimate the incidence (overall and by age group and gender) of unexplained SCD, and 3) to determine the risk of unexplained SCD associated with pro-arrhythmic drug use in patients with co-morbid cadiovascular diseases.Methodology: A community-based matched case-control study will be performed. Cases will be identified from the Institute of Legal Medicine of Catalonia and index date-, health centre-, gender- and age-matched controls will be obtained from the epidemiological database of primary care medical records (SIDIAP). The study will include all suddenly died patients who have had an autopsy that foundno clear cause of death occurred in the last 4 years in the study area in Catalonia. The information on drug exposure, co-variables and risk factors of both cases and controls will be also obtained from the SIDIAP database. The odds ratio and 95% confidence intervals of all groups of drugs potentially causing unexplained SCD will be calculated using techniques of conditional logistic regression analysis.

Study status

Planned

Research institutions and networks

Institutions

University of Girona

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Institution

Translab Research Group

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dolors Capellà

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2014

Actual: 15/01/2014

Study start date

Planned: 15/10/2014

Date of final study report

Planned: 31/01/2017

Sources of funding

- Other

More details on funding

Instituto de Salud Carlos III

Study protocol

FIS_2013_V2.pdf (197.34 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Main objective: To determine the risk of unexplained sudden cardiac death (SCD) associated with proarrhythmic drug use. Secondary objectives: To describe and compare with controls the main characteristics of patients with unexplained SCD. To estimate the incidence of unexplained SCD. To determine the risk of unexplained SCD associated with pro-arrhythmic drug use in patients with cadiovascular dis

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C01) CARDIAC THERAPY

CARDIAC THERAPY

(J01) ANTIBACTERIALS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

(R06) ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

(A04) ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

(N05) PSYCHOLEPTICS

PSYCHOLEPTICS

(N06) PSYCHOANALEPTICS

PSYCHOANALEPTICS

(C03) DIURETICS

DIURETICS

Medical condition to be studied

Sudden cardiac death

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

5500

Study design details

Outcomes

Risk of suddent death associated to the use of cardiac and noncardiac proarrhythmic drugs (drugs that prolong the QT interval, that cause extreme bradycardia, positive chronotropic drugs, drugs causing hydroelectrolytic disturbances), Incidence of sudden cardiac death (global, by groups of age and by gender).Risk of sudden death in patients with cardiovascular diseases and risk of the interaction between cardiovascular diseases and use of proarrhythmic drugs

Data analysis plan

OR and 95% CI through conditional logistic regression

Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No