Atrial fibrillation and heart failure associated to gabapentin and pregabalin

First published: 05/09/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15048

Study ID

28035

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Based on a pilot study performed in 2014, a cohort study and a review of the database of voluntary reporting of the Spanish System of Pharmacovigilance (SSPh) will be performed.Cohort studySix cohorts of all individuals ≥65 years-

old and naïve of cardiovascular medications starting treatment with gabapentin (GP), pregabalin (PG), alprazolam, diazepam, an NSAID, or an analgesic opiate (reference group) between 1 January and 31 March 2015 will be studied. Patients with previous use of cardiovascular medications or antithrombotic drugs in the six months before the index date will be excluded. The index date will be the date of the prescription claim of the drug qualifying for being a member of the corresponding cohort.For atrial fibrillation (AF) the primary variable will be a first claim of an oral anticoagulant or an antiplatelet agent. Secondary variables will be first claims of an OAC or an APA plus an antiarrhythmic drug, an OAC, any cardiovascular medicine or an OAC or an APA, and the former except statins. For heart failure (HF) the primary variable will be a first claim of a diuretic. The secondary variable will be a combination of claims of the following: cardiac glycosides, antiarrhythmic drugs of class I or class III, diuretics, ß-adrenergic blocking agents, selective Ca channel blockers with direct cardiac effects, ACEI, ARB-2, or vasodilating agents.Patients will be stratified into three groups: those who start treatment with the medication of interest without an NSAID, those who start with both the medication of interest and an NSAID, and those to whom the medication of interest is added to an NSAID already dispensed in the 6 months before.Relative risks of AF and of HF will be computed. Stratified analyses will be performed by age, sex, co-treatments, and dose.Analysis of the SSPh databaseThe reports of cardiac arrhythmia and HF attributed to GP or PG will be identified and their clinical course will be examined.

Study status

Finalised

Research institutions and networks

Institutions

Fundació Institut Català de Farmacologia (FICF)

Spain

First published: 29/03/2010

Last updated: 17/09/2019

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Fundació Institut Català de Farmacologia (FICF)

Spain

First published: 29/03/2010

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Gerència de Farmàcia, CatSalut Travessera de Les Corts 139, Barcelona

Contact details

Study institution contact

Joan-Ramon Laporte jrl@icf.uab.cat

Study contact

jrl@icf.uab.cat

Primary lead investigator

Joan-Ramon Laporte

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/12/2014

Actual: 29/12/2014

Study start date

Planned: 04/05/2015

Actual: 04/05/2015

Data analysis start date

Planned: 04/05/2015

Actual: 04/05/2015

Date of interim report, if expected

Planned: 01/03/2016

Actual: 01/03/2016

Date of final study report

Planned: 25/07/2016

Actual: 25/07/2016

Sources of funding

- Other

More details on funding

Catalan Health Service

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the association between exposure to gabapentin or pregabalin and the risk of atrial fibrillation or heart failure.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX12) gabapentin

gabapentin

(N03AX16) pregabalin

pregabalin

Medical condition to be studied

Atrial fibrillation

Cardiac failure acute

Population studied

Short description of the study population

Patients ≥ 65 years of age starting treatment with either gabapentin or pregabalin between January 1 and March 31, 2015, free of cardiovascular disease, and who did not receive the alternate study medications.

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

29000

Study design details

Outcomes

For atrial fibrillation (AF) the primary variable will be a first claim of an oral anticoagulant (or an antiplatelet agent. For heart failure (HF) the primary variable will be a first claim of a diuretic. For atrial fibrillation secondary variables will be first claims of an OAC or an APA plus an antiarrhythmic drug, an OAC, any cardiovascular medicine or an OAC or an APA, and the former except statins. For heart failure the secondary variable will be a combination of claims of various cardiovascular drug groups.

Data analysis plan

Patients will be stratified into three groups: those who start treatment with the medication of interest without an NSAID, those who start with both the medication of interest and an NSAID, and those to whom the medication of interest is added to an NSAID already dispensed in the 6 months before.Relative risks and their corresponding two-sided 95% confidence intervals of AF and of

HF will be computed. Stratified analyses will be performed by age, co-treatments and dose.

Documents

Study results

Drug Safety GP-PG i FA.pdf(1003.45 KB)

Study publications

Ortiz de Landaluce L, Carbonell P, Asensio C, Escoda N, López P, Laporte JR. Ga…

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown