Prescribing of digoxin for long-term use in atrial fibrillation in France, Germany and the UK during 2000-2014

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32487

EU PAS number

EUPAS32486

Study ID

32487

DARWIN EU® study

No

Study countries

☐ France

Germany

Study description

This study analyses prescribing of digoxin between 2000 and 2014 and focuses on patients with atrial fibrillation. The study includes overall digoxin prescribing, digoxin prescribing in patients with atrial fibrillation, and digoxin prescribing in patients with atrial fibrillation without heart failure. Results are analysed by gender and age group (75 years or older and less than 75 years).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hedenmalm Karin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/05/2015

Actual: 02/05/2015

Study start date

Planned: 22/05/2015

Actual: 22/05/2015

Data analysis start date

Planned: 02/06/2015

Actual: 02/06/2015

Date of final study report

Planned: 17/06/2015

Actual: 17/06/2015

Sources of funding

- EMA

Study protocol

Digoxin Protocol_20150617_001.pdf(511.72 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To study prescribing of digoxin in patients with atrial fibrillation

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DIGOXIN

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Atrial fibrillation patients receiving a prescription of digoxin for oral use, excluding products that contain digoxin in combination with another active substance, recorded in the IMS Disease Analyser in France and Germany.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

19000

Study design details

Data analysis plan

The yearly prevalence of prescribing of digoxin will be estimated from the number of patients with a prescription and the total number of patients with a consultation during the time period.

Data management

Data sources

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