Utilisation of low-dose rivaroxaban in patients with atherosclerotic cardiovascular disease in the united kingdom and the netherlands

First published: 07/07/2022

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48112

EU PAS number

EUPAS48079

Study ID

48112

DARWIN EU® study

No

Study countries

☐ Netherlands

☐ United Kingdom

Study description

This study will describe the patterns in prescribing of low-dose Rivaroxaban in people diagnosed with ASCVD following the publication of the COMPASS trial, NICE and ESC recommendations. A time series analysis will be conducted in the UK CPRD Aurum data and Dutch PHARMO Database Network database, to describe the prescribing or dispensing of low-dose (2.5mg twice daily) Rivaroxaban in people with ASCVD from January 2015 to February 2022. Monthly counts of the prevalence of low-dose Rivaroxaban users and incidence of new users will be calculated in the two data sources. An interrupted time series analysis (ITS) analysis using segmented Poisson regression modelling will be conducted to estimate whether or not there was a change in prescribing of Rivaroxaban following each intervention. Several comparisons between users and non-users of low-dose rivaroxaban will characterise the patients, based on relevant comorbidities, concomitant medication user and demographic information. Associations between these covariates and the probability of receiving the prescription will be examined in a logistic regression model.

Study status

Ongoing

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Hunt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2021

Actual: 01/09/2021

Study start date
Planned: 01/11/2021

Actual: 01/11/2021

Date of final study report
Planned: 30/06/2022

Sources of funding

- Other

More details on funding

PhD project

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To compare the trends of the utilisation of low-dose rivaroxaban over the period 2015-2022, before and after guideline changes, in two European countries

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

RIVAROXABAN

Medical condition to be studied

Arteriosclerosis

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

1300000

Study design details

Outcomes

Incidence of the new (incident) use of low-dose rivaroxaban

Data analysis plan

An ITS analysis will be used to determine whether the introduction of the Netherland's National Health Care Institute (Zorginstituut Nederland, 29/01/2019) and UK's National Institute for Health and Care Excellence (NICE, 17/10/2019) recommendations had an impact on utilisation. The primary analysis compared the periods pre- (from 01/01/2015 until the national guideline change "intervention") and post-intervention (from intervention until the end of data collection) using a segmented Poisson regression analysis and per database. For the estimates of the effects of intervention, 95% confidence intervals (CI) and Wald p-values will be estimated. Chi-square and t-tests were used to evaluate differences in patient characteristics for the users versus non-users. Associations between the covariates and the probability of odds of low-dose rivaroxaban use were examined using a logistic regression model to estimate the odd ratio and corresponding 95% CI.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

PHARMO Data Network

Data sources (types)

Drug dispensing/prescription data

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