Risk of stroke and other cardiovascular events among warfarin-treated atrial fibrillation patients – a nationwide cohort study in Finland (FinWAF)

First published: 19/09/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4700

Study ID

18730

DARWIN EU® study

No

Study countries

☐ Finland

Study description

This is a retrospective database linkage study using patient information system data from hospital laboratory databases with linkage to nationwide registers. The study population consists of all atrial fibrillation patients using warfarin with INR measurements in selected hospital district areas in Finland between 01-Jan-2007 and 31-Dec-2009. The main objective is to investigate and compare risk of stroke, systemic thromboembolism, myocardial infarction, bleeding events and mortality among atrial fibrillation patients in relation to International Normalized Ratio levels.

Study status

Finalised

Research institutions and networks

Institutions

EPID Research Oy

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pasi Korhonen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/10/2012

Study start date

Planned: 05/05/2014

Actual: 16/05/2014

Date of final study report

Planned: 31/12/2015

Actual: 31/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Study protocol

ER12-9441 cv185266-prot 20130514.pdf(1.39 MB)

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 investigate and compare risk of stroke, systemic thromboembolism, myocardial infarction, bleeding events and mortality among atrial fibrillation patients in relation to International Normalized Ratio levels: under 2.0, 2.0-3.0, and over 3.0.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

WARFARIN

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

All atrial fibrillation patients using warfarin with INR measurements in selected hospital district areas in Finland between 01-Jan-2007 and 31-Dec-2009. Patients who have purchased warfarin (ATC code B01AA03) between 01-Jan-

2007 and 31-Dec-2009, have at least one INR measurement between 01-Jan-2007 and 31-Dec-2009, and have ICD-10 diagnosis I48 for AF between 01-Jan-2005 and 31-Dec-2009 were included.

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)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation

Estimated number of subjects

32000

Study design details

Outcomes

Stroke, Other systemic thromboembolic events excluding stroke, Myocardial infarction, Bleeding events, Mortality (all-cause), Mortality (stroke), Mortality (myocardial infarction), Mortality (systemic thromboembolic events excluding stroke), Mortality (bleeding events), anemia and renal impairment

Data analysis plan

Stratified incidence rates with 95% CIs will be estimated for each endpoint within the strata of the INR levels, time in therapeutic INR range (TTR) categories, and other covariates.The crude and adjusted hazard ratio (HR) estimates with 95% CIs and P-values will be estimated within the INR levels and TTR categories using the conventional Cox’s proportional hazards model adjusting for other covariates. For INR the category 2.0–3.0 will be used as the reference category. Similarly for TTR the category ≥ 60% of time will be used as the reference category.

Documents

Study results

ER 9441_ENCePP_study report synopsis_20160624.pdf(228.5 KB)

Study publications

Lehto M, Niiranen J, Korhonen P, Mehtälä J, Khanfir H, Hoti F, Lassila R, Raati…

Lehto M, Niiranen J, Korhonen P, Mehtälä J, Khanfir H, Hoti F, Lassila R, Raati…

Raatikainen P, Niiranen J, Korhonen P, Mehtälä J, Khanfir H, Lassila R, Lehto M…

Data management

ENCePP Seal

Composition of steering group and observers

EUPAS4700-4725.pdf(53.47 KB)

Signed code of conduct checklist

Annex2_Checklist_ER12-9441_filled 2013-09-18_signed_blackandwhite.pdf (199.58 KB)

Signed checklist for study protocols

ER12-9441 ENCePPChecklistforStudyProtocols BMS version 1 14May2013 20130618 signed blackandwhite.pdf(191.54 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring, National Reimbursement Register, Finnish Care Register, National Causes of Death Register, Finnish Cancer Registry

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