

# 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

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### Study ID

18730

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### DARWIN EU® study

No

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### Study countries

 Finland

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### 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.

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## 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

[pasi.korhonen@epidresearch.com](mailto:pasi.korhonen@epidresearch.com)

## Primary lead investigator

Pasi Korhonen

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 29/10/2012

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### Study start date

Planned: 05/05/2014

Actual: 16/05/2014

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### 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

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### **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.

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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with atrial fibrillation

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### **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

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### **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  $\geq 60\%$  of time will be used as the reference category.

## Documents

### Study results

[ER 9441\\_ENCePP\\_study report synopsis\\_20160624.pdf](#) (228.5 KB)

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### 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...](#)

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## Data management

### ENCePP Seal

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.

### Composition of steering group and observers

[EUPAS4700-4725.pdf](#) (53.47 KB)

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### Signed code of conduct checklist

[Annex2\\_Checklist\\_ER12-9441\\_filled 2013-09-18\\_signed\\_blackandwhite.pdf](#)  
(199.58 KB)

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## Signed checklist for study protocols

ER12-9441 ENCePPChecklistforStudyProtocols BMS version 1 14May2013

20130618 signed blackandwhite.pdf (191.54 KB)

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## Data sources

### Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

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### 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

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### Check completeness

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown