Risk of subsequent cardiovascular events in patients discharged after myocardial infarction - Perseus (PERSEUS)

First published: 04/05/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8205

Study ID

47380

DARWIN EU® study

No

Study countries

☐ Finland

Study description

Myocardial infarction affects about 5000 patients in Finland per year. Almost 20% of them die within one year after the event. Among the Nordic countries, cardiovascular death rates are the highest in Finland. Current guidelines advise to treat myocardial infarction patients with 12-month dual antiplatelet treatment. An ongoing PEGASUS-TIMI 54 clinical study aims to survey the advantages of longer use of ticagrelor and acetylsalicylic acid in secondary prevention. The aim of the present study is to describe the risk development and risk factors of subsequent cardiovascular events in patients discharged from hospital after myocardial infarction. The study questions focus on patients surviving more than one year without subsequent myocardial infarction or stroke and on patients with known additional risk factors. Pre-specified subgroup analyses in populations mimicking the PEGASUS-TIMI 54 study population in a real-life setting will be performed to enable comparison of real-life and randomised study settings.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 04/11/2014

Study start date

Planned: 01/09/2015

Actual: 12/08/2015

Data analysis start date

Planned: 01/09/2015

Actual: 15/10/2015

Date of final study report

Planned: 30/06/2016

Actual: 17/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca Nordic Baltic

Study protocol

ER-9502_AZ PERSEUS_protocol for pharmacoepidemiological study_v10_20150402.pdf(1.06 MB)

ER-9502_AZ PERSEUS_protocol for pharmacoepidemiological study_v10_20150402_signatures.pdf(1.19 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Astra Zeneca: D1843R00244, EPID Research: ER-9502

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The main objective is to describe the risk development and risk factors of subsequent cardiovascular events in patients discharged from hospital after myocardial infarction. We study all patients alive one week after the discharge, and because the mortality is high during the first year, the main focus is in patients surviving without subsequent myocardial infarction or stroke more than one year.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute myocardial infarction

Population studied

Short description of the study population

Myocardial infarction patients with 12-month dual antiplatelet treatment.

Age groups

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

Other

Special population of interest, other

Myocardial infarction patients

Estimated number of subjects

44000

Study design details

Outcomes

Myocardial infarction (ICD-10 I21-I22), Stroke (total) (ICD-10 I61-64), Cardiovascular mortality (death due to ICD-10 I21-I22, I61-64, I50, I48, I20.0), Composite end-point (deaths due to MI, stroke or cardiovascular mortality causes specified above), Overall mortality (death from any cause), Heart failure (ICD-10 I50), Atrial fibrillation (ICD-10 I48), Unstable angina pectoris (ICD-10 I20.0), Major bleedings (ICD-10 D62, D68.3, I60, J94.2, K22.1, K22.3, K22.6, K25.0, K25.2, K25.4, K25.6, K26.0, K26.2, K26.4, K26.6, K27.0, K27.4, K27.6, K28.0, K28.2, K28.4, K28.6, K29.0, K62.5, K63.1, K63.3, K92.0-K92.2, R04, R31, S06.4-S06.6)

Data analysis plan

R language will be used for in data management for creating the analysis database and in statistical analysis for creating tabulations and graphics as well as in all statistical modelling. If a variable is totally missing it is excluded from the analysis. If a variable is missing for only some of the patients a missing data category is added and used in the analysis. The principles of the statistical analysis by objectives are outlined in protocol. More detailed statistical analysis plans will be written separately.

Documents

Study results

ER-9502-AZ-PERSEUS_EnCePP_1of3.pdf(5.5 MB)

ER-9502-AZ-PERSEUS_EnCePP_2of3.pdf(3.98 MB)

ER-9502-AZ-PERSEUS_EnCePP_3of3.pdf(3.24 MB)

Study publications

Kytö V, Prami T, Khanfir H, Hasvold P, Reissell E, Airaksinen J. Usage of PCI a…

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.

Conflicts of interest of investigators

ER-9502_Annex5_DoIForm_clinical experts_signed.pdf(1.44 MB)

ER-9502_Annex5_DoIForm_EPID and sponsors_signed.pdf(1.72 MB)

Composition of steering group and observers

EUPAS8205-9505.pdf(56.36 KB)

Signed code of conduct

ER-9502_Annex3_Declaration_20150407_signed.pdf(388.58 KB)

Signed code of conduct checklist

ER-9502_Annex2_Checklist_20150504_signed.pdf(857.85 KB)

Signed checklist for study protocols

ER-9502_ENCePPChecklistforStudyProtocolsJan2013_20150402_signed.pdf (612.96 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Causes of Death Registry, National Prescription Register including drug purchases and reimbursement decisions, National Hospital Care Register, National register for institutionalizations (other than hospitalizations)

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