A retrospective cohort study to investigate the initiation and persistence of dual antiplatelet treatment after acute coronary syndrome in a Finnish setting – THALIA

First published: 31/03/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6161

Study ID

47383

DARWIN EU® study

No

Study countries

☐ Finland

Study description

Myocardial infarction affects about 5000 new patients in Finland every year. Approximately 20% of these patients die within one year after the event. Dual antiplatelet treatment (DAPT) with low dose acetylsalicylic acid and oral antiplatelet is recommended for patients with acute coronary syndromes. Guidelines recommend DAPT inhibition to be maintained up to over 12 months unless contraindications are present. New oral antiplatelets (OAP) have recently been introduced in the market in the Nordic countries. It is not known how the patient selection for different DAPT treatments and no-DAPT treatment happen. Neither are the persistence of OAP treatments, switch patterns between different OAP treatments, nor patient adherence to OAP treatments understood. The main objective of this study is to characterize and describe the patients treated with DAPT vs. non-DAPT treated patients, and the switch patterns and discontinuation rates of DAPT treatments. Approximately 200 000 patients discharged from Finnish hospitals following admission for unstable angina pectoris or myocardial infarction in 2009-2013 will be studied by using data from nationwide patient registers.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

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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: 23/01/2014

Study start date

Planned: 04/08/2014

Actual: 07/10/2014

Data analysis start date

Planned: 01/05/2015

Actual: 18/05/2015

Date of final study report
Planned: 29/04/2016

Actual: 15/10/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca Nordic Baltic

Study protocol

ER13-9468 AZ THALIA protocol 10 20140318_signed_smaller.pdf(458.07 KB)

ER13-9468 AZ THALIA protocol 20 20140703_smaller.pdf(966.34 KB)

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to characterize and describe the patients treated with DAPT vs. non-DAPT treated patients, and the switch patterns and discontinuation rates of DAPT treatments.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC04) clopidogrel

clopidogrel

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

Medical condition to be studied

Angina unstable

Acute myocardial infarction

Population studied

Short description of the study population

Finnish adult patients hospitalized for unstable angina pectoris or acute MI alive at discharge in 2009-2013.

Inclusion Criteria

Study population consisted of patients discharged alive from Finnish hospitals following admission for unstable angina pectoris (ICD-10: I20.0) or myocardial infarction (ICD-10: I21) between 01 Jan 2009 and 15 Dec 2013.

Exclusion Criteria

Age less than 18 years at hospital discharge for acute coronary syndrome

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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)

Special population of interest

Other

Special population of interest, other

Angina pectoris patients

Estimated number of subjects

190000

Study design details

Data analysis plan

Drug treatment patterns in the study populations will be described as:- Proportion of patients with OAP medication.- Proportion of patients treated with different OAPs (any OAP and specific OAPs) for 3 months, 6 months, 9 months or 12 months after index day.- Switch patterns of OAP medication.- Discontinuation rates and switch patterns of OAP medication within 12 months after index day.- Medication possession rate.The study patients will be characterized in terms of:- Age- Gender- Time spent in the hospital before discharge at index date- Prior cardiovascular history within five years before index date - Interventions associated with the index event - Cardiovascular morbidity during follow-up associated with prolongation, switch or discontinuation of DAPT treatment - Major co-morbidities - Other medications- Type of hospital- Calendar year

Documents

Study results

ER-9468_AZ Thalia_Non Interventional Study Report_10_20151015_Part 1 - see part 2 at the end of the page.pdf(805.52 KB)

Study report

ER-9468_AZ Thalia_Non Interventional Study Report_10_20151015_1.pdf (805.52 KB)

ER-9468_AZ Thalia_Non Interventional Study Report_10_20151015_2.pdf(1.98 MB)

Study, other information

ER-9468_AZ Thalia_Non Interventional Study Report_10_20151015_2.pdf(1.98 MB)

Study publications

Prami T, Khanfir H, Hasvold P, Reissell E, Airaksinen J, Kytö V. Concomitant us...

Prami T, Khanfir H, Deleskog A, Hasvold P, Kytö V, Reissell E, Airaksinen J. Cl...

Reissell E, Lumme S, Prami T, Halme J, Kytö V, Airaksinen J. Verihiutaleiden es...

Data management

ENCePP Seal

Conflicts of interest of investigators

ER-9468_Annex5_DoIForm_signed.pdf(434.39 KB)

Composition of steering group and observers

EUPAS6161-7229.pdf(51.97 KB)

Signed code of conduct

ER-9468_Annex3_Declaration_20140328_signed.pdf(553.4 KB)

Signed code of conduct checklist

ER-9468_Annex2_Checklist_20140328_signed.pdf(202.15 KB)

Signed checklist for study protocols

ER13-9468 ENCePPChecklistforStudyProtocolsJan2013_20140317_signed_black and white.pdf(181.89 KB)

Data sources

Data source(s), other

Finnish Hospital Care Register (HILMO), Social HILMO, Prescription Register, Causes of Death Registry

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