Incidence and pattern description of gastrointestinal, skin, genital, corneal, and mucosal erosions, ulcerations, perforations, haemorrhages, fistulas, abscesses, delayed wound healing and death among patients treated with nicorandil with and without diverticular disease

First published: 21/04/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS13205

Study ID

23413

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study is to quantify the time-related risk (i.e., the incidence) and patterns of erosions, ulcerations, perforations, haemorrhages, abscesses, fistulae, delayed wound healing in patients treated with nicorandil (including but not restricted to gastrointestinal, skin, ocular, mucosal, anal, alone or in multiple locations), and death in a real world setting, together with the exploration of high risk subgroups (including patients with diverticular disease), other risk factors, and a dose & time effect assessment.

Study status

Finalised

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Communication Center Merck KGaA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2015

Actual: 02/12/2015

Study start date

Planned: 01/05/2016

Actual: 15/08/2016

Date of final study report

Planned: 01/12/2016

Actual: 20/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA, - Chugai Pharmaceutical Co. Ltd and Sanofi-Aventis

Study protocol

20180328_EMR200101_502_EnCepP_Final protocol_Redacted.pdf (8.13 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

The primary purpose is to determine the time-related frequency (i.e. the incidence) and patterns of Perforation, Ulcer, Fistula, Abscess, Erosion, Diverticulosis, Diverticulitis, Death, Delayed wound healing, hemorrhages (PUFAEDH) in patients with angina who are receiving Nicorandil treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

NICORANDIL

Medical condition to be studied

Angina pectoris

Population studied

Short description of the study population

Adult patients registered in NHS who have a diagnosis of angina pectoris between April 1995 to November 2014 and receive an initial Nicorandil prescription.

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 angina pectoris

Estimated number of subjects

40000

Study design details

Outcomes

Incidence Rates: The incidence rates will be calculated using the number of patients presenting with an outcome of interest and the number of events of interest divided by the number of person-years at risk between the index date and the end date of the exposure period, and linked to the event or patterns of

events of interest. The secondary analytic phase will concentrate on patients who had a first PUFAEDH within the 3 months before first Nicorandil prescription (prevalent condition during the baseline period) versus those who did not. Incidence rates for further unique or multiple PUFAEDH and their 95% CI per 100,000 person-years, in patients using Nicorandil will be calculated.

Data analysis plan

Descriptive analytics will be provided for the following variables: age, gender, Nicorandil dose, treatment duration, calendar year, Charlson´s comorbidity index, history or existence of any outcome of interest, diabetes, Helicobacter pylori infection, Zollinger-Ellison syndrome, smoking and use of NSAIDs (including acetylsalicylic acid), diverticular disease, heart failure, alcohol use, use of corticosteroids, selective serotonin re-uptake inhibitors (SSRIs), trauma, impaired blood circulation, bacterial, viral or fungal infections, tumours. Continuous variables will be summarized as average, standard deviation, median, Q1 and Q3. Dichotomous variables will be summarized as sums, proportions and percentages.

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.

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

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