Non-interventional post-authorisation safety study of pattern of use of Nordic Aprotinin (Nordic Aprotinin Patient Registry)

First published: 23/10/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11384

Study ID

40238

DARWIN EU® study

No

Study countries

Austria

Belgium

Denmark

Finland

France
Germany
Ireland
Netherlands
Sweden
United Kingdom

Study description

The Nordic Aprotinin Patient Registry is a multicentre, non-interventional Post Authorisation Safety Study with active surveillance via patient exposure registry. Nordic will supply Nordic Aprotinin only to centres that perform cardiac surgery on cardio-pulmonary bypass and which commit to enrol in the Nordic Aprotinin Patient Registry (participating centres). The Nordic Aprotinin Patient Registry is designed to be easy-to-use and to fit with standard clinical practice. The Registry is intended to record utilisation information on virtually all patients at cardiac surgery centres exposed to the product beginning from the day that Nordic Aprotinin becomes available to the market, and continuing for at least three years thereafter. Nordic will provide appropriate training and support to facilitate implementation of the Registry at all participating centres. Nordic will encourage all participating centres to treat only patients conforming to the authorised indications for Nordic Aprotinin. According to the national legislation of the countries involved, Nordic will carefully monitor the number of cases in which Nordic Aprotinin is given to patients having surgery outside the authorised use and will collect data on these patients via the Registry (use outside cardiac surgery is expected to be negligible due to the limitation of supply to cardiothoracic centres) however if there is any such use, it will be monitored carefully and discussed in the PSUR. The proposed Registry will provide information on the number of patients who receive Nordic Aprotinin by centre, indication (cardiac surgical procedure, indication features) for which Nordic Aprotinin was administered, and the conditions of use, including dose

and adherence to instructions for administration in the approved SmPC. Interim and progress reports will be provided to the PRAC (and the National Competent Authorities if required) and will include summary tables of analyses of patterns of use.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stefan De Hert

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/12/2015

Actual: 07/12/2015

Study start date
Planned: 30/06/2015

Actual: 26/02/2016

Data analysis start date
Planned: 07/01/2020

Actual: 07/01/2020

Date of interim report, if expected
Actual: 04/05/2018

Date of final study report
Planned: 31/12/2020

Actual: 19/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nordic Group B.V.

Study protocol

Aprotinin - PRAC PASS protocol updated 11-03-2015.pdf (1.03 MB)

Aprotinin - PRAC PASS protocol amended 26MAR2020.pdf (8.2 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

1. Monitor the pattern of use and record utilisation information2. Measure the incidence of the following adverse events3. Measure the effectiveness of risk minimisation measures as described in the RMP and close monitoring of adherence to the SmPC recommendations

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post Authorisation Safety Study, Active surveillance

Study drug and medical condition

Medicinal product name, other

TRASYLOL 10,000 KIU/ml, injectable solution

Medical condition to be studied

Death

Thromboembolectomy

Myocardial infarction

Cerebrovascular accident

Renal failure

Anaphylactic reaction

Population studied

Short description of the study population

All patients exposed to Nordic Aprotinin at all participating cardiac surgical centre fulfilling criteria of the restricted distribution in participating countries in Europe.

Inclusion Criteria:

- All patients exposed to Nordic Aprotinin at all participating cardiac surgical centre fulfilling criteria of the restricted distribution in participating countries in Europe.

Exclusion Criteria:

- None

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

5268

Study design details

Outcomes

- Death- Myocardial infarction (fatal and non-fatal)- Renal failure (fatal and non-fatal)- Renal failure with and without aminoglycoside use- Stroke (fatal and non-fatal)- Other embolic or thrombotic event (fatal and non-fatal)- Blood loss: requiring blood product transfusion, requiring re-operation- Blood product transfusion- Anaphylaxis

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Data analysis plan

All data analyses will be performed by Dendrite Clinical Systems together with Nordic after the Key Data are completed. Analysed data will be reviewed by an Independent Data Safety Monitoring Committee, involving at least four national coordinating investigators.The analysis of data from the Registry will be descriptive, and all information will be reported in summary tables. Summary data will be provided for all variables collected and the data will be reported overall, by country, and if required by centre. The intention is to focus on those variables most pertinent to assessing compliance with approved labelling and instructions for appropriate use, including use ofheparin and monitoring of anticoagulation. The data will also be reviewed for any safety signals. The outcomes to be included in each report will include at least the primary outcomes. Overall reports will be synchronised with PSUR scheme and timelines.

Documents

Study results

NAPaR - EJA 2022.pdf (794.13 KB)

NP_25001_NAPaR_ DSMC_Final_20210531 - Abstract.pdf (21.98 KB)

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 sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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