An observational cohort study of the risk of thromboembolic events among adult patients treated with KCENTRA® compared with plasma for urgent reversal of vitamin K antagonist therapy in the setting of acute major bleeding (REVERSAL)

First published: 10/03/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41527

EU PAS number

EUPAS8472

Study ID

41527

DARWIN EU® study

No

Study countries

☐ United States

Study description

A cohort study in a large integrated US health care system with the aim to evaluate whether rates of thromboembolic events (TEE) and other outcomes vary following treatment with KCENTRA versus plasma in adults hospitalized for urgent reversal of vitamin K antagonist (VKA) therapy in the setting of acute major bleeding.

Study status

Finalised

Research institutions and networks

Institutions

Kaiser Permanente Northern California Oakland, CA, USA, Kaiser Permanente Southern California Pasadena, CA, USA

Contact details

Study institution contact

Alan Go

Study contact

alan.s.go@kp.org

Primary lead investigator

Trial Registration Coordinator

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/01/2014

Study start date

Actual: 15/03/2014

Data analysis start date

Planned: 14/08/2020

Actual: 30/06/2020

Date of interim report, if expected

Actual: 30/09/2014

Date of final study report

Planned: 15/05/2021

Actual: 19/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CSL Behring

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To estimate the risk of confirmed TEE within 45 days after the index date for patients treated with KCENTRA compared to patients treated with plasma among those without a recent history of TEE.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Kcentra

Medical condition to be studied

Haemorrhage

Haemorrhagic disorder

Population studied

Short description of the study population

Adult patients treated with KCENTRA® and plasma for urgent reversal of vitamin K antagonist therapy in the setting of acute major bleeding.

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)

Estimated number of subjects

2875

Study design details

Outcomes

Risk of thromboembolic events (TEE) for patients without a recent history of TEE, Risk of thromboembolic events,Risk of death from any cause

Data analysis plan

Incidence rates with associated 95% confidence intervals will be calculated for each outcome of interest by treatment type. Multivariable analyses will be conducted to examine the independent association between treatment type and each outcome of interest, with adjustment for relevant potential confounders and cluster effects, as well as possible time-dependent confounding.

Data management

Data sources

Data source(s), other

KPNC and KPSC Virtual Data Warehouse United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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