A Retrospective Chart-Review Study to Evaluate the Safety, Effectiveness and Dosing of Dalteparin for Treatment of Venous Thromboembolism (VTE) in Neonates

First published: 19/11/2021

Last updated: 13/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS42367

Study ID

50681

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This non-interventional study (NIS) utilizing secondary (i.e., existing) data from routine clinical care is designed to characterize the safety, effectiveness and dosing of dalteparin in neonates treated for VTE. This NIS is designated as a Post-Authorization Safety Study and is a Post-Marketing Requirement to the FDA

Study status

Finalised

Research institutions and networks

Institutions

Kantar Health

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Institution

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Muhammad Younus

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/07/2021

Actual: 17/12/2019

Study start date

Planned: 01/01/2021

Actual: 06/01/2022

Data analysis start date

Planned: 03/05/2022

Actual: 17/05/2022

Date of final study report

Planned: 31/12/2022

Actual: 15/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A6301097_FRAGMIN PROTOCOL FINAL_04 JUN 2020 _EU PAS Register.pdf
(471.13 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

A6301097

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

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Among neonates (≤ 28 days old, and ≥ 35 weeks gestation) treated with dalteparin for VTE, characterize the safety, effectiveness and dosing (starting dose and optimal therapeutic dose) and corresponding anti-Xa assay levels.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Name of medicine, other

Fragmin

Anatomical Therapeutic Chemical (ATC) code

(B01AB04) dalteparin

dalteparin

Medical condition to be studied

Embolism venous

Population studied

Short description of the study population

The study population involved neonates aged ≤ 28 days exposed to dalteparin for the treatment of venous thromboembolism (VTE) in the UK between January 2010 and December 2021.

Inclusion criteria:

• Neonates aged ≤ 28 days at the time of dalteparin initiation and born at gestational age ≥35 weeks

• Diagnosis of VTE, which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), based on acceptable imaging modalities including compression ultrasound with doppler (CUD), computed tomography with/without venography (CT/CTV), magnetic resonance imaging with/without venography (MRI/MRV), conventional venography (CV), conventional pulmonary angiogram (CPA), ventilation-perfusion (V/Q) scan, spiral CT angiography (SCTA)

• Received ≥ 1 dose of dalteparin for the treatment of VTE

Exclusion criteria:

• Patients with bleeding disorders, including, but not limited to platelet

dysfunction, disseminated intravascular coagulation, hemophilia, idiopathic thrombocytopenic purpura, or von Willebrand disease.

Age groups

Term newborn infants (0 – 27 days)

Special population of interest

Other

Special population of interest, other

Venous thromboembolism patients

Estimated number of subjects

12

Study design details

Data analysis plan

Descriptive analyses (no formal hypothesis-testing) will be conducted to address study objectives. Frequencies and percentages to describe categorical variables and means and SDs (or medians with IQRs, where appropriate) for continuous or discrete variables will be calculated.

Documents

Study results

A6301097_FRAGMIN_STUDY ABSTRACT_1.0_EU PAS Register.pdf(179.86 KB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Paper medical records at hospitals

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