Physician Adherence to Fondaparinux Prescribing Information for Patients with Superficial Vein Thrombosis (SVT) of the Lower Limbs (115280)

First published: 05/06/2014

Last updated: 28/05/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS6655

Study ID

42081

DARWIN EU® study

No

Study countries

Germany

Greece

Slovenia

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/10/2012

Actual: 23/10/2012

Study start date
Planned: 23/10/2012

Actual: 23/10/2012

Date of final study report
Planned: 30/09/2014

Actual: 26/08/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

GSK Fondaparinux SVT Protocol_Amendment 2 - 10July13_final.pdf (571.05 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

Other

If ‘other’, further details on the scope of the study

Retrospective chart review

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to evaluate physicians’ adherence to fondaparinux prescribing information for the treatment of patients with Superficial Vein Thrombosis (SVT) without concomitant Deep Vein Thrombosis (DVT)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

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

FONDAPARINUX SODIUM

Population studied

Short description of the study population

Patients prescribed fondaparinux to treat their superficial vein thrombosis (SVT).

Inclusion Criteria

(1) Diagnosis of SVT

(2) Prescribed fondaparinux for the treatment of SVT

(3) Age 18 years or older

Exclusion Criteria

(1) Patients should not have been involved in any clinical trial that could influence SVT treatment during the observational period

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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

Superficial vein thrombosis (SVT) patients

Estimated number of subjects

500

Study design details

Outcomes

The primary outcome measure will be the percentage of patients for whom both an ultrasound (or other objective measure) was performed in order to rule out concomitant DVT prior to patients commencing fondaparinux therapy and who were prescribed the recommended dose (2.5mg, or 1.5mg) of fondaparinux. This will be evaluated overall and per country. The proportion of patients with SVT of the lower limbs treated with fondaparinux, for whom an ultrasound, or other diagnostic imaging procedure, was performed in order to rule out concomitant DVT prior to patients commencing fondaparinux therapy and the proportion of patients with SVT of the lower limbs treated with fondaparinux, for whom either 2.5mg or 1.5mg fondaparinux was prescribed.

Data analysis plan

All statistical analyses will be conducted in Statistical Analysis Software (SAS) v9.1 or later. The proportion of patients treated according to the prescribing information for fondaparinux (the adherence rate) will be estimated using

generalized estimating equations (GEEs). Adherence estimates with confidence intervals will be derived using GEEs overall and for each country. The GEE will explicitly take into account the nesting of patients, per physician, within a medical practice.

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)

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