# 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

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**Study start date**
Planned: 23/10/2012

Actual: 23/10/2012

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**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

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**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

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**Study type:**

Non-interventional study

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**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

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**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

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**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