PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prevention of Thromboembolic Events – European Registry in Venous Thromboembolism

Trial Acronym

PREFER in VTE

URL of the trial

[---]*

Brief Summary in Lay Language

In this registry, it is intended to assess the characteristics and management of patients with venous thromboembolism and to assess health care resources and estimated costs in relation to this disease. This registry is purely observational and no additional examinations will be carried out. The patient's medical treatment by their doctor will not be influenced.

Brief Summary in Scientific Language

This study is a prospective non-interventional study to assess the characteristics and management of patients with venous thromboembolism and the use of health care resources and the estimated costs for 12 months following confirmed first-time and/or recurrent venous thromboembolism diagnosis. In addition, existing anti-coagulant treatment patterns, patient pathways, clinical outcomes, treatment satisfaction, and health related quality of life in a naturalistic setting will be described.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004795**
- Date of Registration in DRKS: **2013/03/15**

DRKS-ID: **DRKS00004795**
Date of Registration in DRKS: **2013/03/15**

- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **837.553.12 (8654) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- MedDRA: **Venous Thromboembolism**
- ICD10: **I82 - Other venous embolism and thrombosis**

Interventions/Observational Groups

- Arm 1: **- Patient characteristics**
  - History of thromboembolic/bleeding events and diagnose of acute venous thromboembolism
  - Drug utiliation / use pattern of drugs for treatment of venous thromboembolism and prevention of related events
  - health related quality of life
  - resource consumption / Health Care Utilization

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health economics**
- Assignment: **Single (group)**
- Phase: **N/A**
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Health economics**

Assignment: **Single (group)**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary objective of this study is to assess the 12 month direct healthcare resource use and estimated costs following acute first time (initial) or recurrent venous thromboembolism. In addition, detailed insight on the characteristics and management of patients with acute venous thromboembolism (in particular deep vein thrombosis and/or pulmonary embolism) with focus on prevention of related events (e. g. bleeding or other complications, recurrence of deep vein tmbosis/pulmonary embolism, myocardial infarction, stroke, systemic embolic event, post thrombotic syndrome, percutaneous coronary intervention, coronary artery bypass graft, and death) will be collected.

Secondary Outcome

- To describe the treatment satisfaction (PACT Q2), health related quality of life (EQ 5D), and clinical outcomes following first time (initial) or recurrent venous thromboembolism. Timepoints: Baseline, 1, 3, 6 and 12 month(s) after baseline
- To explore relationship between anticoagulants and duration of therapy and resource use, estimated costs, treatment satisfaction (PACT Q), and health related quality of life (EQ D5), and clinical outcomes.
- To explore geographic variations in the management of patients with venous thromboembolism

Countries of recruitment

- DE **Germany**
- AT **Austria**
- CH **Switzerland**
- IT **Italy**
- ES **Spain**
- UK **United Kingdom**

UK **United Kingdom**

- FR **France**

Locations of Recruitment

- Medical Center **Marienhospital Steinfurt, Steinfurt**
- Medical Center **Vinzenzkrankenhaus Hannover, Hannover**
- Doctor's Practice **Hamburg**
- Doctor's Practice **Nürnberg**
- Doctor's Practice **Mannheim**
- Doctor's Practice **Hof/Saale**
- Doctor's Practice **Mühldorf**
- Doctor's Practice **Baesweiler**
- Medical Center **Herzklinik Ulm, Ulm**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Altenburg**
- Doctor's Practice **Cottbus**
- Doctor's Practice **Osnabrück**
- Doctor's Practice **Chemnitz**
- Doctor's Practice **München**
- Doctor's Practice **Augsburg**
- Doctor's Practice **Dahlwitz-Hoppegarten**
- Medical Center **Krankenhaus Dresden-Friedrichstadt, Dresden**
- Doctor's Practice **Lauffen**
- Medical Center **Carl-von-Basedow-Klinikum, Merseburg**
- Doctor's Practice **Freiburg im Breisgau**
- Doctor's Practice **Dornstadt**
- Medical Center **Kreiskrankenhaus Mechernich, Mechernich**
- Doctor's Practice **Schönberg**
- Doctor's Practice **Nordhausen**
- Doctor's Practice **Bad Salzungen**
- Medical Center **St. Marien-Hospital, Lünen**
- Doctor's Practice **Bremerhaven**
- Medical Center **Jüdisches Krankenhaus Berlin, Berlin**

- Doctor's Practice **Biebesheim**
- Medical Center **Bethesda Krankenhaus Bergedorf, Hamburg**
- Doctor's Practice **Bernsdorf**
- Doctor's Practice **Coburg**
- Doctor's Practice **Oberhausen**
- Doctor's Practice **Leverkusen**
- Medical Center **Klinikum am Bruderwald, Bamberg**
- Medical Center **Eduardus Krankenhaus, Köln**
- Doctor's Practice **Huy**
- Medical Center **Privatklinik Dr. Schindlbeck, Herrsching**
- University Medical Center **Medizinische Hochschule Hannover, Hannover**
- Medical Center **Krankenhaus Neu-Mariahilf, Göttingen**
- Doctor's Practice **Riesa**
- Doctor's Practice **Hannover**
- University Medical Center **Uniklinik Dresden, Dresden**
- Doctor's Practice **Görlitz**
- Doctor's Practice **Pirna**
- Medical Center **Klinikum Ludwigshafen, Ludwigshafen am Rhein**
- Doctor's Practice **Lebach**
- Doctor's Practice **Erlangen**
- Medical Center **Klinikum Lippe-Detmold, Detmold**
- Doctor's Practice **Frankenthal**
- Doctor's Practice **Neubrandenburg**
- Medical Center **Vivantes Klinikum Neukölln, Berlin**
- Doctor's Practice **Aachen**
- University Medical Center **Universitäts-Hautklinik Tübingen, Tübingen**
- Doctor's Practice **Weißenfels**
- University Medical Center **Universitätsklinikum Magdeburg, Magdeburg**
- University Medical Center **Universitätsklinikum Lübeck, Lübeck**
- Medical Center **Klinikum Darmstadt, Darmstadt**
- Medical Center **Vivantes Klinikum Spandau, Berlin**
- Medical Center **Vivantes Humboldt Klinikum, Berlin**

- University Medical Center **Universitätsklinikum Kiel, Kiel**
- Doctor's Practice **Grimma**
- Medical Center **Helios Klinikum, Erfurt**
- Medical Center **Medinos Klinik, Sonneberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/24**
- Target Sample Size: **4500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Established acute initial or recurrent VTE
• In hospitals, surgical or non-surgical wards or specialised office-based centres
• Written informed consent for participation in the registry (including telephone follow-ups)
• Not simultaneously participating in a double blind interventional study

Exclusion criteria

No explicit medical exclusion criteria are stated

Addresses

- **Primary Sponsor**

  Daiichi-Sankyo Europe GmbH
  81379 München
  Germany

  Telephone: **[---]***
  Fax: **[---]***

Primary Sponsor

Daiichi-Sankyo Europe GmbH
81379 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Daiichi Sankyo Europe GmbH
Mr. Dr. Wolf-Peter Wolf
Zielstattstraße 48
81379 München
Germany

Telephone: **+49-(0)89-78 08 308**
Fax: **[---]***
E-mail: **wolf-peter.wolf at daiichi-sankyo.eu**
URL: **[---]***

■ **Contact for Public Queries**

Daiichi Sankyo Europe GmbH
Mr. Dr. Wolf-Peter Wolf
Zielstattstr. 48
81379 München
Germany

Telephone: **+49-(0)89-70 08 308**
Fax: **[---]***
E-mail: **wolf-peter.wolf at daiichi-sankyo.eu**
URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Daiichi Sankyo Europe GmbH
Zielstattstr. 48
81379 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***

Commercial (pharmaceutical industry, medical engineering industry, etc.)

Daiichi Sankyo Europe GmbH
Zielstattstr. 48
81379 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/08/28**

Trial Publications, Results and other documents

- Further trial documents **Agnelli G, Gitt AK, Bauersachs R, Fronk EM, Laeis P, Mismetti P, Monreal M, Willich SN, Wolf WP, Cohen AT; PREFER in VTE investigators. The management of acute venous thromboembolism in clinical practice - study rationale and protocol of the European PREFER in VTE Registry.**
- Paper **[---]***

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*