Rivaroxaban in the Treatment of Venous Thromboembolism (VTE) in Cancer Patients

This study is currently recruiting participants. (see Contacts and Locations)

Verified March 2016 by AIO-Studien-gGmbH

Sponsor:
AIO-Studien-gGmbH

Collaborators:
Charite University, Berlin, Germany
Bayer

Information provided by (Responsible Party):
AIO-Studien-gGmbH

ClinicalTrials.gov Identifier:
NCT02583191

First received: October 15, 2015
Last updated: March 18, 2016
Last verified: March 2016
History of Changes

Purpose

The purpose of this study is to show feasibility (efficacy and safety) of Rivaroxaban in the treatment of VTE in cancer patients in comparison to the standard treatment with low molecular weight heparin (LMWH).

Tumor patients with active cancer and newly diagnosed thromboembolic events are randomised to receive either Rivaroxaban or the standard treatment with low-molecular heparin.

Condition	Intervention	Phase
Venous Thromboembolism Cancer	Drug: Rivaroxaban Drug: low-molecular heparine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: CONKO_011/ AIO-SUP-0115/Ass.: Rivaroxaban in the Treatment of Venous Thromboembolism (VTE) in Cancer Patients - a Randomized Phase III Study

Resource links provided by NLM:

MedlinePlus related topics: Blood Thinners

Drug Information available for: Rivaroxaban

U.S. FDA Resources

Further study details as provided by AIO-Studien-gGmbH:

Primary Outcome Measures:

- Patient-reported treatment satisfaction (convenience) with Rivaroxaban in the treatment of acute VTE in cancer patients in comparison with the standard treatment with low molecular weight heparin [Time Frame: From randomization to 4 weeks after treatment start]
  [Designated as safety issue: No]

Secondary Outcome Measures:

- Rate of symptomatic venous thrombembolism-recurrence within 3 months exploratory analysis for patients with treatment [Time Frame: From randomization to 3 months after treatment start] [Designated as safety issue: Yes]
- Exploratory analysis for "time on treatment" [Time Frame: From randomization to 12 weeks after treatment start]
  [Designated as safety issue: No]
- Subgroup analysis with regard to rate of Pulmonary embolism, venous thrombembolism recurrence and bleedings (major, clinically relevant, minor) according to stratification characteristics [Time Frame: From randomization to end of follow up (up to 24 weeks)]
  [Designated as safety issue: Yes]

- Rate of myocardial infarction and ischemic stroke [Time Frame: From randomization to end of follow up (up to 24 weeks)] [Designated as safety issue: Yes]
- Compliance of patients (adherence) [Time Frame: From randomization to end of follow up (up to 24 weeks)] [Designated as safety issue: No]
- Overall mortality 3 and 6 months after randomization [Time Frame: From randomization to 3 and 6 months after randomization] [Designated as safety issue: No]
- Quality of Life (Spitzer Index (Spitzer 1981), Anticlot Treatment Scale (ACTS) and TSQM [Time Frame: 4 weekly, up to 12 weeks] [Designated as safety issue: No]
- Rate of clinically relevant bleeding (major + clinically relevant non major) within 3 months [Time Frame: From randomization to 3 months after randomization] [Designated as safety issue: Yes]
- Rate of minor bleedings within 3 months [Time Frame: From randomization to 3 months after randomization] [Designated as safety issue: Yes]

Estimated Enrollment:	450
Study Start Date:	March 2016
Estimated Study Completion Date:	March 2018
Estimated Primary Completion Date:	March 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Rivaroxaban Arm A: Rivaroxaban	Drug: Rivaroxaban Rivaroxaban 15 mg twice daily for 21 days, followed by 20 mg once daily over a period of 3 months Other Name: Xarelto
Active Comparator: low-molecular heparine Arm B: standard treatment with low-molecular heparine	Drug: low-molecular heparine LMWH in therapeutic dosage (1-2× daily s.c.) according to standards of the individual study center, using licensed dosages, e.g. • Enoxaparin 1 mg/kg BW twice daily • Tinzaparin 175 I.E./kg BW once daily • Dalteparin 200 I.E./kg BW once daily

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Newly diagnosed and objectively confirmed acute venous thromboembolism
- Active malignancy
- Life expectancy of at least 6 months
- Performance-Status according to Karnofsky Performance Scale ≥ 70 %
- Patient's compliance and geographical situation allowing an adequate follow up
- platelets ≥ 100.000 /µl, INR < 1.5, PTT < 40 sec.
- written informed consent of the patient prior to any procedure in connection with the study
- male and female patients with an age of at least 18 years

Exclusion Criteria:

- therapeutic anticoagulation > 96 hours prior to study treatment
- known allergic reactions against the study drugs or the substances included therein
- known conditions associated with high risk of bleeding, known history of hemorrhagic diathesis
- acute clinically relevant bleeding in the last 2 weeks
- any history of spontaneous major/cerebral bleeding
- history of heparin induced thrombocytopenia II
- pregnant or breast-feeding women. Women of child-bearing potential must have a negative pregnancy test performed < 7 days prior to start of the treatment
- severe renal insufficiency (GFR < 30 ml/min)
- liver disease with coagulation impairment, including Child B and C
- cirrhosis
- acute medical illness
- treatment of the underlying cancer with experimental therapies

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02583191

Contacts

Contact: Aysun Karatas, Dr. aysun.karatas@aio-studien-ggmbh.de

Contact: Hanno Riess, Prof. Dr.

Locations

Germany

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Contact: Christoph Roderburg, Dr.

Sponsors and Collaborators

AIO-Studien-gGmbH

Charite University, Berlin, Germany

Bayer

More Information

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Last Updated:	March 18, 2016
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Additional relevant MeSH terms:

Thromboembolism
Venous Thromboembolism
Embolism and Thrombosis
Vascular Diseases
Cardiovascular Diseases
Rivaroxaban
Factor Xa Inhibitors
Antithrombins
Serine Proteinase Inhibitors
Protease Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Anticoagulants

ClinicalTrials.gov processed this record on July 04, 2016