A Study to Evaluate the Efficacy and Safety of Rivaroxaban Venous Thromboembolism (VTE) Prophylaxis in Ambulatory Cancer Participants

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

Verified November 2016 by Janssen Research & Development, LLC

Sponsor:
Janssen Research & Development, LLC

Collaborator:
Bayer

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT02555878

First received: September 18, 2015
Last updated: November 25, 2016
Last verified: November 2016
History of Changes

Purpose

The purpose of this study is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal deep vein thrombosis (DVT), asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal pulmonary embolism (PE), incidental PE, and venous thromboembolism (VTE)-related death in ambulatory adult participants with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.

Condition	Intervention	Phase
Neoplasms	Drug: Rivaroxaban Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator)
Primary Purpose: Prevention

Official Title: Efficacy and Safety of Rivaroxaban Prophylaxis Compared With Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism

Resource links provided by NLM:

MedlinePlus related topics: Cancer

Drug Information available for: Rivaroxaban

U.S. FDA Resources

Further study details as provided by Janssen Research & Development, LLC:

Primary Outcome Measures:

- Primary Efficacy Composite Endpoint is Time From Randomization to First Occurrence of Objectively Confirmed Symptomatic and Asymptomatic Lower Extremity Proximal DVT,Symptomatic Upper Extremity DVT,Symptomatic Non-Fatal PE,Incidental PE,VTE-Related Death [Time Frame: From Randomization to the Day 180 visit as Adjudicated by an Independent blinded CEC] [Designated as safety issue: No]

  Diagnosis of DVT confirmed by compression ultrasonography and diagnosis of PE through computerized tomography or ventilation/perfusion lung scan.

- The Primary Safety Objective of This Study is to Assess the Major Bleeding Events as Defined by ISTH [Time Frame: From the Time of Randomization to 2 Days After the Last Dose of Study Drug] [Designated as safety issue: Yes]

Major bleeding is defined as clinically overt bleeding that is associated with: A reduction in hemoglobin of 2 gram per deciliter (g/dL) or more, or A transfusion of 2 or more units of packed red blood cells or whole blood, or occurrence at a critical site defined as intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, retroperitoneal, or death.

Secondary Outcome Measures:

- The Key Secondary Efficacy Endpoints Include the Following: 1) Symptomatic VTE Events (DVT/PE) and VTE-Related Deaths and 2) All-cause Mortality [Time Frame: From the time of randomization to the Day 180 visit] [Designated as safety issue: No]
- Secondary Safety Endpoints Include the Proportion of Clinically Relevant Non-Major Bleeding, Minor Bleeding, any Bleeding (Defined as Major, Clinically Relevant Non-Major, and Minor Bleeding as defined by ISTH) [Time Frame: From the Time of Randomization to Two Days After the Last Dose of Study Drug] [Designated as safety issue: No]

  According to International Society on Thrombosis & Haemostasis (ISTH) definition.

- Number of Participants with Adverse Events (AEs) and Serious AEs [Time Frame: Screening up to follow-up (30 days after last dose administration)] [Designated as safety issue: Yes]

  Adverse events or serious adverse events will be collected and entered into the eCRF. All SAEs that are not outcome events occurring during the study must be reported to the appropriate sponsor contact person by study-site personnel within 24 hours of their knowledge of the event.

Estimated Enrollment:	700
Study Start Date:	September 2015
Estimated Study Completion Date:	January 2018
Estimated Primary Completion Date:	January 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Rivaroxaban Participants will be administered rivaroxaban 10 milligram (mg) tablet orally once daily for 180 days.	Drug: Rivaroxaban Rivaroxaban 10 milligram (mg) tablet will be administered orally once daily for 180 days.
Experimental: Placebo Participants will be administered matching placebo tablet orally once daily for 180 days.	Drug: Placebo Placebo tablet will be administered orally once daily for 180 days.

Detailed Description:
This is a multicenter, randomized, double-blind, placebo-controlled, parallel-group, superiority study comparing the efficacy and safety of rivaroxaban with placebo for primary prophylaxis of venous thromboembolism (VTE) in ambulatory adult participants, with various cancer types who are scheduled to initiate systemic cancer therapy. The study consists of 3 Phases: Screening Phase (14 Days), double-blind treatment Phase (180 Days) and follow up Phase (30 Days). The duration of participation in the study for each participant is approximately 32 weeks.

Eligibility

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

Criteria

Inclusion Criteria:

- Have histologically confirmed solid malignancy including but not limited to: pancreas, lung, stomach, colon, rectum, bladder, breast, ovary, renal or lymphoma (hematologic), with locally advanced or metastatic disease
- Have an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2
- Have a Khorana thromboembolic risk Score greater than or equal to (>=) 2
- Creatinine clearance (CrCl) >= 30 milliliter per minute (mL/min)
- Plan to initiate systemic cancer therapy within plus or minus (+-) 1 week of receiving the first dose of study drug with the intention of receiving systemic cancer therapy during the double-blind treatment period for an intended duration determined by the treating oncologist according to standard protocols of clinical care

Exclusion Criteria:

- Diagnosis of primary brain tumors
- Known history of brain metastases
- Bleeding diathesis, hemorrhagic lesions, active bleeding, and other conditions with a high risk for bleeding
- Hematologic malignancies with the exception of lymphoma
- Platelet count less than (<) 50,000/millimeter^3 (mm^3), Life expectancy of less than or equal to (<=) 6 months

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: NCT02555878

Contacts

Contact: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions: JNJ.CT@sylogent.com

Show 112 Study Locations

Sponsors and Collaborators

Janssen Research & Development, LLC

Bayer

Investigators

Study Director: Janssen Research & Development, LLC Clinical Trial Janssen Research & Development, LLC

More Information

Additional Information:

To learn how to participate in this trial please click here.

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ClinicalTrials.gov Identifier:	NCT02555878 History of Changes
Other Study ID Numbers:	CR107047 **39039039STM4001** 2015-001630-21
Study First Received:	September 18, 2015
Last Updated:	November 25, 2016
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Canada: Health Canada Germany: Federal Institute for Drugs and Medical Devices United Kingdom: Medicines and Healthcare Products Regulatory Agency United States: Food and Drug Administration Great Britain: Medicines and Healthcare Products Regulatory Agency Brazil: National Health Surveillance Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment Czech Republic: State Institute for Drug Control Canada: Health Canada - TPD

Keywords provided by Janssen Research & Development, LLC:
Cancer
Rivaroxaban
Venous thromboembolism

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on December 09, 2016