A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to apixaban on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE (ASTER)

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This study has been transitioned to CTIS with ID 2023-509569-19-00 check the CTIS register for the current data. The primary objective of this study is to assess whether abelacimab is non-inferior to apixaban for preventing VTE recurrence at 6...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON51481

Source
ToetsingOnline

Brief title
ANT-007 ASTER

Condition

- Embolism and thrombosis

Synonym
venous thromboembolism

Research involving
Human

Sponsors and support

Primary sponsor: Anthos Therapeutics, Inc.
Source(s) of monetary or material Support: Anthos Therapeutics

Intervention

Keyword: bleeding, cancer associated VTE, venous thromboembolism (VTE) recurrence

Outcome measures

Primary outcome

The primary objective of this study is to assess whether abelacimab is non-inferior to apixaban for preventing VTE recurrence at 6 months post andomization in patients with cancer and recently diagnosed VTE. If non-nferiority is demonstrated, then superiority will be assessed.

Secondary outcome

• To assess whether abelacimab is superior to apixaban for preventing occurrence of the composite of major or CRNM bleeding at 6 months post randomization

• To assess whether abelacimab is superior to apixaban on net clinical benefit defined as survival without VTE recurrence, or major or CRNM bleeding events at 6 months post randomization

• To assess whether abelacimab is superior to apixaban on the rate of permanent treatment discontinuation not due to death at 6 months post randomization

• To assess whether abelacimab is superior to apixaban for preventing occurrence of CRNM bleeding events at 6 months post randomization

• To assess whether abelacimab is superior to apixaban for preventing occurrence of major bleeding events at 6 months post randomization

• To assess whether abelacimab is superior to apixaban for preventing the occurrence of the composite of GI major and GI CRNM bleeding at 6 months post randomization

• To evaluate safety and tolerability of abelacimab relative to apixaban through 6 months post randomization and to assess the incidence of injection site reactions, hypersensitivity reactions and immunogenicity in patients treated with abelacimab

Study description

Background summary

Adult male or female subjects are eligible for study participation if they have confirmed diagnosis of cancer (other than basal-cell or squamous cell carcinoma of the skin) and presentation with acute VTE (venous thromboembolism), for which long-term treatment with direct oral anticoagulants (DOACs) is indicated.

Standard of care treatments in such cases include blood thinners (anticoagulants), such as apixaban (Eliquis®) or low molecular weight heparin, which helps treat blood clots and reduce the risk of complications that blood clots can cause, like a stroke, but they can increase the risk of bleeding.

Abelacimab is an experimental drug also referred to as the *study drug* in this consent, that is being studied for its ability to reduce blood clotting with potentially fewer bleeding events. Abelacimab is an antibody (type of protein made by the immune system) that binds to another protein that plays an important role in blood clot formation.
The purpose of this study is to see if patients taking abelacimab have fewer bleeding events compared to those taking apixaban. Apixaban is approved by Health Authorities in The Netherlands to treat patients with an increased risk of blood clots

Study objective

This study has been transitioned to CTIS with ID 2023-509569-19-00 check the CTIS register for the current data.

The primary objective of this study is to assess whether abelacimab is non-inferior to apixaban for preventing VTE recurrence at 6 months post randomization in patients with cancer and recently diagnosed VTE. If noninferiority is demonstrated, then superiority will be assessed.

Study design

This is a randomized, open-label, blinded endpoint evaluation (PROBE), active controlled study.

Intervention

1. Abelacimab 150 mg iv on Day 1 then, starting approximately 30 days later, abelacimab 150 mg sc every month for an additional 5 months (sc administration planned on Days 31, 61, 91, 121, and 151 ± 5 days).

2. Apixaban 10 mg bid for 7 days, followed by 5 mg bid for a total period of 6 months. If a patient receives apixaban at a dose of 10 mg bid without interruption during screening and is randomized to the apixaban treatment arm, the on-study treatment duration with the 10 mg bid dose will be shortened so that no patient receives more than 7 days of the 10 mg bid dose of apixaban.

Study burden and risks

Side effects from study medication abelacimab and apixaban.

Injection site reaction

Risks associated with blood collection include pain, swelling and/or bruising at the insertion site of the needle.

ECG - a patient may have a mild irritation, slight redness, or itching at the sites on the skin where the recording patches are placed.

Abelacimab may help to effectively treat the clot in the body and help prevent blood clots from forming again. However, there is no guarantee that there will be any benefit to the subject.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Male or female subjects >=18 years old or another legal maturity age according to the country of residence
• Confirmed diagnosis of cancer (by histology or adequate imaging modality), other than basal-cell or squamous-cell carcinoma of the skin alone with one of the following:
o Active cancer, defined as either locally active, regionally invasive, or metastatic cancer at the time of randomization, and/oro Currently receiving or having received anticancer therapy (radiotherapy, chemotherapy, hormonal therapy, any kind of targeted therapy or any other anticancer therapy) in the last 6 months.
• Confirmed symptomatic or incidental proximal lower limb acute DVT (i.e., popliteal, femoral, iliac, and/or inferior vena cava vein thrombosis) and/or a

confirmed symptomatic PE, or an incidental PE
in a segmental, or larger pulmonary artery. Patients are eligible within 72 hours from diagnosis of the qualifying VTE.
• Anticoagulation therapy with a therapeutic dose of DOAC for at least 6 months is indicated.
• Able to provide written informed consent.

Exclusion criteria

• Thrombectomy, insertion of a caval filter or use of a fibrinolytic agent to treat the current (index) occurrence of DVT and/or PE
• More than 72 hours of pre-treatment with therapeutic doses of UFH, LMWH, fondaparinux, DOAC, or other anticoagulants
• An indication to continue treatment with therapeutic doses of an anticoagulant other than that used for VTE treatment prior to randomization (e.g., atrial fibrillation, mechanical heart valve, prior VTE)
• Platelet count <50,000/mm3
• PE leading to hemodynamic instability (systolic blood pressure [BP] <90 mmHg or shock)
• Acute ischemic or hemorrhagic stroke or intracranial hemorrhage within 4 weeks preceding screening
• Brain trauma, or a cerebral or a spinal cord surgery in the 4 weeks preceding screening
• Need for aspirin in a dosage of more than 100 mg/per day or any other antiplatelet agent alone or in combination with aspirin
• Primary brain cancer or untreated intracranial metastases
• Acute myeloid or lymphoid leukemia
• Bleeding requiring medical attention at the time of randomization or in the preceding 4 weeks
• Planned major surgery at baseline
• Eastern Cooperative Oncology Group (ECOG) performance status of 3 or 4 at screening
• Life expectancy <3 months at randomization
• Calculated creatinine clearance (CrCl) <30 mL/min
• Hemoglobin less than 8 g/dL
• Acute hepatitis, chronic active hepatitis, liver cirrhosis; or an alanine aminotransferase level 3 times or more and/or bilirubin level 2 times or more higher the upper

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2023
Enrollment:	85
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Abelacimab
Generic name:	Abelacimab
Product type:	Medicine
Brand name:	Eliquis
Generic name:	APIXABAN
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-03-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2022
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2023
Application type:	Amendment
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Approved WMO Date:	07-02-2023
Application type:	Amendment
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Approved WMO Date:	04-04-2023
Application type:	Amendment
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Approved WMO Date:	13-10-2023
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Approved WMO Date:	24-11-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2023-509569-19-00
EudraCT	EUCTR2021-003076-14-NL
CCMO	NL80373.018.22