A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE (Magnolia)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II , Fase III	356
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética, farmacoeconómica	NO

Información

Identificador
2024-513992-42-00 (CTIS)

Cod. Protocolo
ANT-008

Transicionado 2021-003085-12

Área terapéutica
Enfermedades [C] - Patologías cardiovasculares [C14]|

Enfermedad investigada
venous thromboembolism (VTE) in patients with gastrointestinal/genitourinary cancer

Título Científico

A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE (Magnolia)

Justificación

No aportado

Objetivo Principal

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

Variables de Evaluación Primaria

Time to first event of centrally adjudicated VTE recurrence 6 months post randomization

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Male or female subjects 18 years old or other legal maturity age according to the country of residence
Confirmed GI (colorectal, pancreatic, gastric, esophageal, gastro- esophageal junction or hepatobiliary) or confirmed GU (renal, ureteral, bladder, prostate, or urethra) cancers if: Unresectable, locally advanced, metastatic, or non-

metastatic GI/GU cancer and No intended curative surgery during the study
Confirmed symptomatic or incidental proximal lower limb 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 120 hours from diagnosis of the qualifying VTE.
Anticoagulation therapy with LMWH for at least 6 months is indicated.
Able to provide written informed consent.

Criterios de Exclusión

Thrombectomy, insertion of a caval filter or use of a fibrinolytic agent to treat the current (index) DVT and/or PE. History of heparin-induced thrombocytopenia Infective acute or subacute endocarditis at the time of presentation Primary brain cancer or untreated intracranial metastasis 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 (Cockcroft-Gault equation) at the screening visit Platelet count <50,000/mm3 at the screening visit Hemoglobin <8 g/dL at the screening visit Acute hepatitis, chronic active hepatitis, liver cirrhosis; or an alanine aminotransferase (ALT) 3 x and/or bilirubin 2 x upper limit of normal (ULN) at the screening visit in absence of clinical explanation Uncontrolled hypertension (systolic BP >180 mm Hg or diastolic BP >100 mm Hg) despite antihypertensive treatment More than 120 hours of pre-treatment with therapeutic doses of UFH, LMWH, or other anticoagulants. Women of child-bearing potential (WOCBP) who are unwilling or unable to use highly effective contraceptive measures during the study from screening up to 3 days after last treatment of dalteparin or 100 days after administration of abelacimab (See Section 5.3.6 for highly effective contraceptive measures) Sexually active males with sexual partners of childbearing potential must agree to use a condom or other reliable contraceptive measure up to 3 days after last treatment of dalteparin or 100 days after administration of abelacimab. Pregnant or breast-feeding women History of hypersensitivity to any of the study drugs (including dalteparin) or its excipients, to drugs of similar chemical classes, or any contraindication listed in the label for dalteparin Subjects with any condition that in the Investigator's judgement would place the subject at increased risk of harm if he/she participated in the study Use of other investigational (not-registered) drugs within 5 half-lives prior to enrollment or until the expected PD effect has returned to baseline, whichever is longer. Participation in academic noninterventional studies or interventional studies testing different strategies or different combinations of registered drugs is permitted. An indication to continue treatment with therapeutic doses of an anticoagulant other than that for VTE treatment prior to randomization (e.g., AF, mechanical heart valve, prior VTE). PE leading to hemodynamic instability (blood pressure [BP] <90 mmHg or shock) Acute ischemic or hemorrhagic stroke or intracranial hemorrhage within 4 weeks of screening Brain trauma or a cerebral or spinal cord surgery or spinal procedures such as lumbar puncture or epidural/spinal anesthesia within 4 weeks of screening Need for aspirin in a dosage of >100 mg/day or any other antiplatelet agent alone or in combination with aspirin Bleeding requiring medical attention at the time of randomization or within the preceding 4 weeks Planned brain, spinal cord, cardiac, vascular, major thoracic and/or major abdominal surgery in the 4 weeks following randomization

Calendario

(Última actualización: 15/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/04/2022	13/09/2022	26/09/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	06/04/2026	No aportado	No aportado	No aportado

Promotor

Anthos Therapeutics Inc. United States

1 Health Plaza

Contact Person

Anthos Therapeutics Information Desk

+16174306940

info@anthostherapeutics.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Centros

Activo (20/09/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

No iniciado (--/--/----)

Clinica Universidad De Navarra

Madrid

MADRID

Oncology

Activo (07/10/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE

Ourense

OURENSE

Activo (16/09/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (12/09/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Activo (27/09/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Activo (17/10/2022)

HOSPITAL DE SABADELL

Sabadell

BARCELONA

Activo (01/09/2022)

HOSPITAL GENERAL UNIVERSITARIO DE ELCHE

Elche/Elx

ALICANTE

Oncology

Activo (16/09/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

No iniciado (--/--/----)

Hospital La Milagrosa S.A.

Madrid

MADRID

Oncology

Activo (10/08/2022)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

Madrid

MADRID

Activo (31/08/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (02/09/2022)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Activo (19/09/2022)

HOSPITAL UNIVERSITARIO DE JAEN

Jaén

JAÉN

No iniciado (--/--/----)

Hospital Universitario Del Vinalopo

Elche

ALICANTE

Oncology

Activo (19/09/2022)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Activo (14/09/2022)

HOSPITAL UNIVERSITARIO LUCUS AUGUSTI

Lugo

LUGO

Activo (04/08/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Activo (24/10/2022)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Activo (20/10/2022)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

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HOSPITAL UNIVERSITARIO VINALOPO

Elche/Elx

ALICANTE

Hematology

Activo (29/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

Activo (14/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

No iniciado (--/--/----)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Oncology

Medicamentos

Abelacimab 150 mg/ml solution for infusion
CONCENTRATE FOR SOLUTION FOR INFUSION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

Fragmin® 5000 IU
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: B01AB04 - DALTEPARINA
Principios Activos: N/A

Experimental

Sin resultados

A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE (Magnolia)

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II , Phase III	356
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomic	NO

Information

Identifier
2024-513992-42-00 (CTIS)

Protocol Code
ANT-008

Transitioned 2021-003085-12

Therapeutic area
Diseases [C] - Cardiovascular Diseases [C14]|

Investigated Disease
venous thromboembolism (VTE) in patients with gastrointestinal/genitourinary cancer

Scientific Title

A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE (Magnolia)

Rationale

Not provided

Main Objective

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

Primary Endpoints

Time to first event of centrally adjudicated VTE recurrence 6 months post randomization

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Male or female subjects 18 years old or other legal maturity age according to the country of residence
Confirmed GI (colorectal, pancreatic, gastric, esophageal, gastro- esophageal junction or hepatobiliary) or confirmed GU (renal, ureteral, bladder, prostate, or urethra) cancers if: Unresectable, locally advanced, metastatic, or non-

metastatic GI/GU cancer and No intended curative surgery during the study
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Able to provide written informed consent.

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Thrombectomy, insertion of a caval filter or use of a fibrinolytic agent to treat the current (index) DVT and/or PE. History of heparin-induced thrombocytopenia Infective acute or subacute endocarditis at the time of presentation Primary brain cancer or untreated intracranial metastasis 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 (Cockcroft-Gault equation) at the screening visit Platelet count <50,000/mm3 at the screening visit Hemoglobin <8 g/dL at the screening visit Acute hepatitis, chronic active hepatitis, liver cirrhosis; or an alanine aminotransferase (ALT) 3 x and/or bilirubin 2 x upper limit of normal (ULN) at the screening visit in absence of clinical explanation Uncontrolled hypertension (systolic BP >180 mm Hg or diastolic BP >100 mm Hg) despite antihypertensive treatment More than 120 hours of pre-treatment with therapeutic doses of UFH, LMWH, or other anticoagulants. Women of child-bearing potential (WOCBP) who are unwilling or unable to use highly effective contraceptive measures during the study from screening up to 3 days after last treatment of dalteparin or 100 days after administration of abelacimab (See Section 5.3.6 for highly effective contraceptive measures) Sexually active males with sexual partners of childbearing potential must agree to use a condom or other reliable contraceptive measure up to 3 days after last treatment of dalteparin or 100 days after administration of abelacimab. Pregnant or breast-feeding women History of hypersensitivity to any of the study drugs (including dalteparin) or its excipients, to drugs of similar chemical classes, or any contraindication listed in the label for dalteparin Subjects with any condition that in the Investigator's judgement would place the subject at increased risk of harm if he/she participated in the study Use of other investigational (not-registered) drugs within 5 half-lives prior to enrollment or until the expected PD effect has returned to baseline, whichever is longer. Participation in academic noninterventional studies or interventional studies testing different strategies or different combinations of registered drugs is permitted. An indication to continue treatment with therapeutic doses of an anticoagulant other than that for VTE treatment prior to randomization (e.g., AF, mechanical heart valve, prior VTE). PE leading to hemodynamic instability (blood pressure [BP] <90 mmHg or shock) Acute ischemic or hemorrhagic stroke or intracranial hemorrhage within 4 weeks of screening Brain trauma or a cerebral or spinal cord surgery or spinal procedures such as lumbar puncture or epidural/spinal anesthesia within 4 weeks of screening Need for aspirin in a dosage of >100 mg/day or any other antiplatelet agent alone or in combination with aspirin Bleeding requiring medical attention at the time of randomization or within the preceding 4 weeks Planned brain, spinal cord, cardiac, vascular, major thoracic and/or major abdominal surgery in the 4 weeks following randomization

Calendar

(Last Update: 15/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/04/2022	13/09/2022	26/09/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	06/04/2026	Not aported	Not aported	Not aported

Sponsor

Anthos Therapeutics Inc. United States

1 Health Plaza

Contact Person

Anthos Therapeutics Information Desk

+16174306940

info@anthostherapeutics.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

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ceic@tauli.cat

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Sites

Active (20/09/2022)

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NAVARRA

not initialized (--/--/----)

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Sevilla

SEVILLA

not initialized (--/--/----)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Oncology

Medication

Abelacimab 150 mg/ml solution for infusion
CONCENTRATE FOR SOLUTION FOR INFUSION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

Fragmin® 5000 IU
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

ATC code: B01AB04 - DALTEPARINA
Active Principles: N/A

Experimental

No results