Study of four-factor prothrombin complex concentrate, OCTAPLEX, in patients with acute major bleeding on direct oral anticoagulant (DOAC) therapy with factor Xa inhibitor

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	Sujetos incapaces de otorgar consentimiento , En situación de urgencia	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	260
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia	NO

Información

Identificador

2024-515485-14-00 (CTIS)

Cod. Protocolo

LEX-210

Transicionado 2021-000740-21

Área terapéutica

Enfermedades [C] - Hematología [C15]|

Enfermedad investigada

Acute major bleeding in patients receiving DOAC therapy with factor Xa inhibitor

Título Científico

Study of four-factor prothrombin complex concentrate, OCTAPLEX, in patients with acute major bleeding on direct oral anticoagulant (DOAC) therapy with factor Xa inhibitor.

Justificación

No aportado

Objetivo Principal

To demonstrate superior haemostatic effectiveness of OCTAPLEX dosed at 50 IU/Kg body weight vs. 15 IU/Kg body weight for emergency reversal of the anticoagulant effect of DOACs in patients with major bleeding associated with factor Xa inhibition.

Variables de Evaluación Primaria

The proportion of patients in whom OCTAPLEX demonstrates haemostatic effectiveness, i.e., binary outcome of effective (rating of excellent or good) or non-effective (rating of poor/none) in management of major bleeding events.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the effect of OCTAPLEX on thrombin generation in patients with acute major bleeding on DOAC therapy with factor Xa inhibitor.
To evaluate the safety of OCTAPLEX in patients with acute major bleeding on DOAC therapy with factor Xa inhibitor.

Variables de Evaluación Secundaria

Change in endogenous thrombin potential (ETP) as measured by thrombin generation assay (TGA) from baseline to 1 hour after OCTAPLEX administration
30-day event rate of thromboembolic events (TEEs) and all-cause mortality
Occurrence of adverse events (AEs) during a 48-hours follow up period after OCTAPLEX administration
Vital signs and laboratory parameters during a 48-hours follow up period after OCTAPLEX administration

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients on oral factor Xa inhibitor therapy and with known or suspected baseline anti-factor Xa activity of at least

100 ng/mL: Patients who received or who are believed by the investigator to have received a dose of oral factor Xa inhibitor and who have a baseline antifactor Xa activity of at least 100 ng/mL according to the locally available test (e.g., chromogenic assay) performed outside of the study as part of standard of care OR -Patients who received or who are believed by the investigator to have received their latest dose of oral factor Xa inhibitor (e.g., rivaroxaban 10 mg, apixaban 2.5 mg, edoxaban 30 mg) 8 hours prior to enrolment OR -Patients who received or who are believed by the investigator to have received their latest dose of oral factor Xa inhibitor (e.g., rivaroxaban 10 mg, apixaban 2.5 mg, edoxaban 30 mg) >8 hours prior to enrolment or at an unknown time, but for whom the investigator suspects a baseline anti-factor Xa activity of at least 100 ng/mL and assesses that the administration of OCTAPLEX is clinically indicated Aged 18 years Patients who have given written informed consent or for whom written informed consent has been obtained from the patient's legally authorised representative on their behalf - Wherever possible, prospective written informed consent will be obtained before enrolment from the patient or, if they are incapable of providing it, from their legally authorised representative;- If prospective written informed consent is not possible, deferred consent procedures will be permitted outside the US if approved by the local ethics committee or otherwise permitted under local regulations;- When deferred consent procedures are used outside the US, written informed consent should be obtained from the patient as soon as they recover the capacity to provide it, or otherwise from their legally authorised representative Patients who have acute major bleeding defined as follows: - Bleeding that is life-threatening or uncontrolled, e.g., with signs or symptoms of haemodynamic compromise, such as severe hypotension, poor skin perfusion, or low cardiac output that cannot be otherwise explained OR - Symptomatic bleeding in critical organs (intracranial, intraspinal, intraocular, gastrointestinal ,retroperitoneal, intra-articular, pericardial, or intramuscular with compartment syndrome) OR - - Acute overt bleeding associated with a fall in haemoglobin (Hgb) level of 2 g/dL, OR a Hgb level 8 g/dL if no baseline Hgb level is available, OR in the opinion of the investigator that the patient's Hgb level will fall to 8 g/dL with resuscitation

Criterios de Exclusión

Patients with Do not resuscitate (DNR) orders
Patients who received ticlopidine within 14 days, prasugrel within 7 days, clopidogrel within 5 days, ticagrelor within 5 days , dipyridamole within 1 day or cangrelor within 1 hour preceding the bleeding event
Patients on enoxaparin therapy for thromboembolic prophylaxis
A score of less than 7 on the Glasgow Coma Scale in non-intubated patients or an estimated intracerebral haematoma volume of more than 60 mL (Patients intubated or sedated at the time of screening may be enrolled if intubation or sedation were done for non-neurologic reasons)
Patients with expected survival of less than 24 hours, in the opinion of the investigator (in collaboration with other medical experts as appropriate per usual local practice)
Patients scheduled to undergo surgery in less than 12 hours, with the exception of minor/surgeries and invasive procedures which are allowed for diagnostic or therapeutic reasons or if intended to address a second (non-index) bleeding event
Patients who are pregnant or breastfeeding at the time of enrolment
Patients previously enrolled in this study
Patients participating in another interventional clinical treatment study currently or during the past 1 month prior to study inclusion
Patients with acute trauma for which reversal of DOAC therapy with factor Xa inhibitor alone would not be expected to control the bleeding event
Hgb decrease without accompanying evidence of source of bleeding
Acute coronary syndrome, ischaemic stroke or venous thromboembolism (VTE) within the preceding 3 months
Patients with a history, within the last 3 months, of disseminated intravascular coagulation (DIC) or hyperfibrinolysis
Patients with a known congenital bleeding disorder
Known inhibitors to coagulation factors II, VII, IX, or X; heparininduced, type II thrombocytopenia; or immunoglobulin A (IgA) deficiency with known antibodies against IgA
Known hypersensitivity to plasma-derived products or heparin
Patients who received haemostatic agents, including plasma, platelets, PCC, activated PCC (aPCC), recombinant factor VIIa, or recombinant factor Xa inactivated-zhzo (andexanet alfa), for the current bleeding event prior to enrolment (antifibrinolytic drugs and local haemostatic agents are allowed)

Calendario

(Última actualización: 19/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
01/07/2022	02/11/2022	09/06/2025	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
22/12/2025	25/02/2026	No aportado	No aportado	26/02/2026

Promotor

Octapharma AG Switzerland

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (15/09/2022)

HOSPITAL UNIVERSITARIO DR. PESET ALEIXANDRE

València

VALENCIA

Anaesthesia and Post-Surgical Critical Care

Activo (04/11/2022)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Critical Care Unit

Activo (06/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Anesthesiology and Critical Care Department

Activo (24/04/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Anesthesiology and Critical Care

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Neurosurgery

Medicamentos

Octaplex 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: B02BD01 - FACTORES DE LA COAGULACION IX, II, VII Y X EN COMBINACION

Principios Activos: N/A

Experimental

Octaplex 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: B02BD01 - FACTORES DE LA COAGULACION IX, II, VII Y X EN COMBINACION

Principios Activos: N/A

Experimental

Sin resultados

Study of four-factor prothrombin complex concentrate, OCTAPLEX, in patients with acute major bleeding on direct oral anticoagulant (DOAC) therapy with factor Xa inhibitor

State	Type of participants	Age Ranges
Finished CT	Incapable subjects of giving consent , In emergency situation	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	260
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness	NO

Information

Identifier
2024-515485-14-00 (CTIS)

Protocol Code
LEX-210

Transitioned 2021-000740-21

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Acute major bleeding in patients receiving DOAC therapy with factor Xa inhibitor

Scientific Title
Study of four-factor prothrombin complex concentrate, OCTAPLEX, in patients with acute major bleeding on direct oral anticoagulant (DOAC) therapy with factor Xa inhibitor.

Rationale

Not provided

Main Objective

To demonstrate superior haemostatic effectiveness of OCTAPLEX dosed at 50 IU/Kg body weight vs. 15 IU/Kg body weight for emergency reversal of the anticoagulant effect of DOACs in patients with major bleeding associated with factor Xa inhibition.

Primary Endpoints

The proportion of patients in whom OCTAPLEX demonstrates haemostatic effectiveness, i.e., binary outcome of effective (rating of excellent or good) or non-effective (rating of poor/none) in management of major bleeding events.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the effect of OCTAPLEX on thrombin generation in patients with acute major bleeding on DOAC therapy with factor Xa inhibitor.
To evaluate the safety of OCTAPLEX in patients with acute major bleeding on DOAC therapy with factor Xa inhibitor.

Secondary Endpoints

Change in endogenous thrombin potential (ETP) as measured by thrombin generation assay (TGA) from baseline to 1 hour after OCTAPLEX administration
30-day event rate of thromboembolic events (TEEs) and all-cause mortality
Occurrence of adverse events (AEs) during a 48-hours follow up period after OCTAPLEX administration
Vital signs and laboratory parameters during a 48-hours follow up period after OCTAPLEX administration

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients on oral factor Xa inhibitor therapy and with known or suspected baseline anti-factor Xa activity of at least

100 ng/mL: Patients who received or who are believed by the investigator to have received a dose of oral factor Xa inhibitor and who have a baseline antifactor Xa activity of at least 100 ng/mL according to the locally available test (e.g., chromogenic assay) performed outside of the study as part of standard of care OR -Patients who received or who are believed by the investigator to have received their latest dose of oral factor Xa inhibitor (e.g., rivaroxaban 10 mg, apixaban 2.5 mg, edoxaban 30 mg) 8 hours prior to enrolment OR -Patients who received or who are believed by the investigator to have received their latest dose of oral factor Xa inhibitor (e.g., rivaroxaban 10 mg, apixaban 2.5 mg, edoxaban 30 mg) >8 hours prior to enrolment or at an unknown time, but for whom the investigator suspects a baseline anti-factor Xa activity of at least 100 ng/mL and assesses that the administration of OCTAPLEX is clinically indicated Aged 18 years Patients who have given written informed consent or for whom written informed consent has been obtained from the patient's legally authorised representative on their behalf - Wherever possible, prospective written informed consent will be obtained before enrolment from the patient or, if they are incapable of providing it, from their legally authorised representative;- If prospective written informed consent is not possible, deferred consent procedures will be permitted outside the US if approved by the local ethics committee or otherwise permitted under local regulations;- When deferred consent procedures are used outside the US, written informed consent should be obtained from the patient as soon as they recover the capacity to provide it, or otherwise from their legally authorised representative Patients who have acute major bleeding defined as follows: - Bleeding that is life-threatening or uncontrolled, e.g., with signs or symptoms of haemodynamic compromise, such as severe hypotension, poor skin perfusion, or low cardiac output that cannot be otherwise explained OR - Symptomatic bleeding in critical organs (intracranial, intraspinal, intraocular, gastrointestinal ,retroperitoneal, intra-articular, pericardial, or intramuscular with compartment syndrome) OR - - Acute overt bleeding associated with a fall in haemoglobin (Hgb) level of 2 g/dL, OR a Hgb level 8 g/dL if no baseline Hgb level is available, OR in the opinion of the investigator that the patient's Hgb level will fall to 8 g/dL with resuscitation

Exclusion criteria

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Known inhibitors to coagulation factors II, VII, IX, or X; heparininduced, type II thrombocytopenia; or immunoglobulin A (IgA) deficiency with known antibodies against IgA
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Calendar

(Last Update: 19/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
01/07/2022	02/11/2022	09/06/2025	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
22/12/2025	25/02/2026	Not aported	Not aported	26/02/2026

Sponsor

Octapharma AG Switzerland

Seidenstrasse 2

Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (15/09/2022)

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València

VALENCIA

Anaesthesia and Post-Surgical Critical Care

Active (04/11/2022)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Critical Care Unit

Active (06/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Anesthesiology and Critical Care Department

Active (24/04/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Anesthesiology and Critical Care

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Neurosurgery

Medication

Octaplex 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: B02BD01 - FACTORES DE LA COAGULACION IX, II, VII Y X EN COMBINACION

Active Principles: N/A

Experimental

Octaplex 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: B02BD01 - FACTORES DE LA COAGULACION IX, II, VII Y X EN COMBINACION

Active Principles: N/A

Experimental

No results