A Study Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Crovalimab for the Management of Acute Uncomplicated VasoOcclusive Episodes (VOE) in Patients With Sickle Cell Disease (SCD)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	55
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2022-502546-26-00 (CTIS)

Cod. Protocolo
BO42452

Transicionado 2020-004840-27

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Sickle Cell Disease

Título Científico
A Phase IB, Randomized, Placebo-Controlled Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Crovalimab for the Management of Acute Uncomplicated VasoOcclusive Episodes (VOE) in Patients

With Sickle Cell Disease (SCD)

Justificación

No aportado

Objetivo Principal

To evaluate the safety of crovalimab compared with placebo

Variables de Evaluación Primaria

Incidence and severity of adverse events, with severity determined according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events, Version 5.0 (CTCAE v5.0)
Change from baseline in targeted vital signs and clinical laboratory test results
Incidence and severity of infusion-related reactions and hypersensitivity

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the pharmacokinetics (PK) of crovalimab
To evaluate the pharmacodynamics (PD) of crovalimab
To evaluate the efficacy of crovalimab compared with placebo
To evaluate the immune response to crovalimab

Variables de Evaluación Secundaria

Serum concentrations of crovalimab over time
Relationships between drug exposure and pharmacodynamics, efficacy, or safety endpoints of crovalimab (patients randomized to crovalimab)
Change over time in PD biomarkers (CH50, free C5, sC5b-9)
Time to improvement of the primary acute uncomplicated VOE from baseline
Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs during the study

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Body weight >=40 kg Confirmed diagnosis of HbSS (SCD genotype of sickle cell anemia) or HbS0 (SCD genotype of sickle cell beta zero thalassemia) Vaccination against Neisseria Meningitidis,, and vaccinations against H. influenzae type B and S. pneumoniae Diagnosis of an acute uncomplicated VOE that requires admission to a hospital/acute medical facility and treatment with parenteral opioid analgesics Adequate hepatic and renal function Participants receiving sickle cell therapies must be on a stable dose for >=28 days

Criterios de Exclusión

More than 10 VOEs within the last 12 months prior to presentation that have required a medical facility visit Pain related to the current VOE ongoing for >48 hours Acute pain related to avascular necrosis, hepatic or splenic sequestration, or priapism, and pain atypical of an acute uncomplicated VOE Transfusion or receipt of blood products within 3 months or current participation in a chronic transfusion protocol Known or suspected hereditary complement deficiency Pregnant or breastfeeding, or intending to become pregnant during the study or within 322 days (approximately 10.5 months) after the study drug administration

Calendario

(Última actualización: 05/12/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/05/2021	09/07/2021	27/09/2021	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
28/08/2023	No aportado	No aportado	31/03/2025	15/08/2025

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

+41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Centros

No iniciado (12/05/2021)

Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

Cerrado (11/11/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Cerrado (19/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Cerrado (05/11/2025)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

Hematología

Cerrado (12/11/2025)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Crovalimab

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

-

Principios Activos: N/A

Experimental

Tiene resultados

A Study Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Crovalimab for the Management of Acute Uncomplicated VasoOcclusive Episodes (VOE) in Patients With Sickle Cell Disease (SCD)

State	Type of participants	Age Ranges
Finished CT	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I	55
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2022-502546-26-00 (CTIS)

Protocol Code
BO42452

Transitioned 2020-004840-27

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

Investigated Disease
Sickle Cell Disease

Scientific Title
A Phase IB, Randomized, Placebo-Controlled Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Crovalimab for the Management of Acute Uncomplicated VasoOcclusive Episodes (VOE) in Patients

With Sickle Cell Disease (SCD)

Rationale

Not provided

Main Objective

To evaluate the safety of crovalimab compared with placebo

Primary Endpoints

Incidence and severity of adverse events, with severity determined according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events, Version 5.0 (CTCAE v5.0)
Change from baseline in targeted vital signs and clinical laboratory test results
Incidence and severity of infusion-related reactions and hypersensitivity

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the pharmacokinetics (PK) of crovalimab
To evaluate the pharmacodynamics (PD) of crovalimab
To evaluate the efficacy of crovalimab compared with placebo
To evaluate the immune response to crovalimab

Secondary Endpoints

Serum concentrations of crovalimab over time
Relationships between drug exposure and pharmacodynamics, efficacy, or safety endpoints of crovalimab (patients randomized to crovalimab)
Change over time in PD biomarkers (CH50, free C5, sC5b-9)
Time to improvement of the primary acute uncomplicated VOE from baseline
Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs during the study

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Body weight >=40 kg Confirmed diagnosis of HbSS (SCD genotype of sickle cell anemia) or HbS0 (SCD genotype of sickle cell beta zero thalassemia) Vaccination against Neisseria Meningitidis,, and vaccinations against H. influenzae type B and S. pneumoniae Diagnosis of an acute uncomplicated VOE that requires admission to a hospital/acute medical facility and treatment with parenteral opioid analgesics Adequate hepatic and renal function Participants receiving sickle cell therapies must be on a stable dose for >=28 days

Exclusion criteria

More than 10 VOEs within the last 12 months prior to presentation that have required a medical facility visit Pain related to the current VOE ongoing for >48 hours Acute pain related to avascular necrosis, hepatic or splenic sequestration, or priapism, and pain atypical of an acute uncomplicated VOE Transfusion or receipt of blood products within 3 months or current participation in a chronic transfusion protocol Known or suspected hereditary complement deficiency Pregnant or breastfeeding, or intending to become pregnant during the study or within 322 days (approximately 10.5 months) after the study drug administration

Calendar

(Last Update: 05/12/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/05/2021	09/07/2021	27/09/2021	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
28/08/2023	Not aported	Not aported	31/03/2025	15/08/2025

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

+41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Sites

not initialized (12/05/2021)

Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

Closed (11/11/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Closed (19/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Closed (05/11/2025)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

Hematología

Closed (12/11/2025)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Crovalimab

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

-

Active Principles: N/A

Experimental

Has results