A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Crovalimab as Adjunct Treatment in Prevention of Vaso-Occlusive Episodes (VOE) in 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) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	88
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2022-502542-28-00 (CTIS)

Cod. Protocolo
BO42451

Transicionado 2020-004839-25

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

Enfermedad investigada
Sickle Cell Disease

Título Científico
A RANDOMIZED DOUBLE-BLIND PHASE IIA STUDY EVALUATING THE EFFICACY, SAFETY,

PHARMACOKINETICS, AND PHARMACODYNAMICS OF CROVALIMAB AS ADJUNCT TREATMENT IN PREVENTION OF VASO-OCCLUSIVE EPISODES (VOE) IN SICKLE CELL DISEASE (SCD)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of crovalimab compared with placebo

Variables de Evaluación Primaria

Annualized rate of medical facility VOEs (AVR)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of crovalimab compared with placebo
To evaluate the safety and tolerability of crovalimab compared with placebo
To evaluate the pharmacokinetics of crovalimab
To evaluate the immune response to crovalimab

Variables de Evaluación Secundaria

Annualized rate of home VOE captured by patient report on a handheld device at home Annualized rate of uncomplicated medical facility VOE Annualized rate of acute chest syndrome (ACS) Annualized rate of days hospitalized for medical facility VOE Annualized rate of days hospitalized for treatment of non-VOE complications of SCD Change in hematologic measures from baseline to Week 49 Time to first medical facility VOE from randomization Change in urinary albumin-creatinine ratio from baseline to Week 49 Change from baseline to Week 49 in tricuspid regurgitant jet velocity (TRV) Proportion of patients with TRV > 2.5 m/s at Week 49 Change from baseline to Week 49 in Patient-Reported Outcomes Measurement Information System (PROMIS)-Fatigue score in adults

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Body weight >=40 kg Male or female with confirmed diagnosis of HbSS (SCD genotype of sickle cell anemia) or HbS0 (SCD genotype of sickle cell beta zero thalassemia) Two or more (>=2) to <=10 documented VOEs in the 12 months prior to randomisation If receiving concurrent SCD-directed therapy, the participant must have been on a stable dose for a minimum of 3 months prior to study enrollment. There should be no plans to modify the participants' dosing throughout the study duration, other than for safety reasons Vaccination against N. meningitides serotypes A, C, W, and Y, and vaccinations against H. influenza type B and S. pneumonia Adequate hepatic and renal function

Criterios de Exclusión

History of hematopoietic stem cell transplant Participating in a chronic transfusion program and/or planning on undergoing an exchange transfusion during the duration of the study History of hypersensitivity, allergic, or anaphylactic reactions to any ingredient contained in the study treatment Hemoglobin <6 g/dL Active systemic bacterial, viral, or fungal infection within 14 days before first drug administration Presence of fever (>=38 degrees Celsius) within 7 days before the first drug administration

Calendario

(Última actualización: 02/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
28/09/2021	06/12/2021	22/02/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
30/05/2024	No aportado	No aportado	25/02/2026	09/04/2026

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Head of CTRM Clinical Trial Regulatory Management, Product Development Regulatory

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global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Activo (06/12/2021)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

No iniciado (28/09/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (04/05/2023)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

Hematología

Cerrado (21/01/2026)

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

Sin resultados

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Crovalimab as Adjunct Treatment in Prevention of Vaso-Occlusive Episodes (VOE) in Sickle Cell Disease (SCD)

State	Type of participants	Age Ranges
Finished CT	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	88
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2022-502542-28-00 (CTIS)

Protocol Code
BO42451

Transitioned 2020-004839-25

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

Investigated Disease
Sickle Cell Disease

Scientific Title
A RANDOMIZED DOUBLE-BLIND PHASE IIA STUDY EVALUATING THE EFFICACY, SAFETY,

PHARMACOKINETICS, AND PHARMACODYNAMICS OF CROVALIMAB AS ADJUNCT TREATMENT IN PREVENTION OF VASO-OCCLUSIVE EPISODES (VOE) IN SICKLE CELL DISEASE (SCD)

Rationale

Not provided

Main Objective

To evaluate the efficacy of crovalimab compared with placebo

Primary Endpoints

Annualized rate of medical facility VOEs (AVR)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of crovalimab compared with placebo
To evaluate the safety and tolerability of crovalimab compared with placebo
To evaluate the pharmacokinetics of crovalimab
To evaluate the immune response to crovalimab

Secondary Endpoints

Annualized rate of home VOE captured by patient report on a handheld device at home Annualized rate of uncomplicated medical facility VOE Annualized rate of acute chest syndrome (ACS) Annualized rate of days hospitalized for medical facility VOE Annualized rate of days hospitalized for treatment of non-VOE complications of SCD Change in hematologic measures from baseline to Week 49 Time to first medical facility VOE from randomization Change in urinary albumin-creatinine ratio from baseline to Week 49 Change from baseline to Week 49 in tricuspid regurgitant jet velocity (TRV) Proportion of patients with TRV > 2.5 m/s at Week 49 Change from baseline to Week 49 in Patient-Reported Outcomes Measurement Information System (PROMIS)-Fatigue score in adults

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Exclusion criteria

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Calendar

(Last Update: 02/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
28/09/2021	06/12/2021	22/02/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
30/05/2024	Not aported	Not aported	25/02/2026	09/04/2026

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Head of CTRM Clinical Trial Regulatory Management, Product Development Regulatory

+41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Active (06/12/2021)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

not initialized (28/09/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Active (04/05/2023)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

Hematología

Closed (21/01/2026)

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

No results