Rollover Study for Patients with Sickle Cell Disease who have Completed a prior Novartis-Sponsored Crizanlizumab Study

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses) , Recién nacidos (0-27 días)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	85
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad	NO

Información

Identificador
2024-510734-41-00 (CTIS)

Cod. Protocolo
CSEG101A2401B

Transicionado 2020-004225-22

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

Enfermedad investigada
Sickle cell disease

Título Científico
An Open-label, Multi-center, Phase IV, Rollover Study for Patients with Sickle Cell Disease who have Completed a

Prior Novartis-Sponsored Crizanlizumab Study

Justificación

No aportado

Objetivo Principal

To allow access of crizanlizumab to patients with SCD who are on crizanlizumab treatment in a Novartis-sponsored study

Variables de Evaluación Primaria

N/A

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the overall safety of crizanlizumab in SCD patients

Variables de Evaluación Secundaria

Frequency, severity and causality of treatment emergent adverse events

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Written informed consent/assent, according to local guidelines, signed by the adult patients.
SCD patient currently enrolled and benefitting from a Novartis-sponsored study receiving crizanlizumab and has fulfilled all the requirements
Patient has demonstrated compliance to the planned visit schedule in the parent study, and in the opinion of the investigator has shown willingness and ability to comply with future visit schedules

Criterios de Exclusión

Patient had permanently discontinued from crizanlizumab study treatment in the parent study before the parent study completion
Ongoing/unresolved treatment-related Grade 3 or higher AEs, and/or any ongoing AE requiring dose interruption
Concurrent participation in any other investigational clinical trial other than the parent study or plan to participate in any other investigational clinical trial
Women of childbearing potential who are unwilling to be on highly effective contraceptives during dosing and until 15 weeks after stopping treatment with crizanlizumab
Pregnant or nursing women

Calendario

(Última actualización: 15/09/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/07/2021	29/10/2021	23/11/2021	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
30/10/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

Activo (29/10/2021)

Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

No iniciado (14/07/2021)

HOSPITAL UNIVERSITARI SON ESPASES

Palma

BALEARES

Activo (01/07/2024)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

No iniciado (14/07/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medicamentos

SEG101

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Sin resultados

Rollover Study for Patients with Sickle Cell Disease who have Completed a prior Novartis-Sponsored Crizanlizumab Study

State	Type of participants	Age Ranges
End of recruitment	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months) , Newborn infants (0-27 days)
Gender	**Phases**	**Expected Participants**
Both	Phase IV	85
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety	NO

Information

Identifier
2024-510734-41-00 (CTIS)

Protocol Code
CSEG101A2401B

Transitioned 2020-004225-22

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

Investigated Disease
Sickle cell disease

Scientific Title
An Open-label, Multi-center, Phase IV, Rollover Study for Patients with Sickle Cell Disease who have Completed a

Prior Novartis-Sponsored Crizanlizumab Study

Rationale

Not provided

Main Objective

To allow access of crizanlizumab to patients with SCD who are on crizanlizumab treatment in a Novartis-sponsored study

Primary Endpoints

N/A

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the overall safety of crizanlizumab in SCD patients

Secondary Endpoints

Frequency, severity and causality of treatment emergent adverse events

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Written informed consent/assent, according to local guidelines, signed by the adult patients.
SCD patient currently enrolled and benefitting from a Novartis-sponsored study receiving crizanlizumab and has fulfilled all the requirements
Patient has demonstrated compliance to the planned visit schedule in the parent study, and in the opinion of the investigator has shown willingness and ability to comply with future visit schedules

Exclusion criteria

Patient had permanently discontinued from crizanlizumab study treatment in the parent study before the parent study completion
Ongoing/unresolved treatment-related Grade 3 or higher AEs, and/or any ongoing AE requiring dose interruption
Concurrent participation in any other investigational clinical trial other than the parent study or plan to participate in any other investigational clinical trial
Women of childbearing potential who are unwilling to be on highly effective contraceptives during dosing and until 15 weeks after stopping treatment with crizanlizumab
Pregnant or nursing women

Calendar

(Last Update: 15/09/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/07/2021	29/10/2021	23/11/2021	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
30/10/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Sites

Active (29/10/2021)

Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

not initialized (14/07/2021)

HOSPITAL UNIVERSITARI SON ESPASES

Palma

BALEARES

Active (01/07/2024)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

not initialized (14/07/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medication

SEG101

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

No results