

A study of elritercept to treat transfusion-dependent anemia due to very low, low, or intermediate risk myelodysplastic syndromes

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase III

Participantes esperados

153

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

Si

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética,
farmacodinamica, dosis

Terapia avanzada

NO

Información

Identificador

2024-516009-22-00 (CTIS)

Cod. Protocolo

KER-050-D301

Área terapéutica

Enfermedades [C] - Hematología [C15]

Enfermedad investigada

myelodysplastic neoplasms/syndromes (MDS)

Título Científico

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Elritercept (KER-050) for the Treatment of Transfusion-Dependent Anemia in Adult Participants with Very Low-, Low-, or Intermediate-Risk Myelodysplastic Syndromes (MDS) (RENEW)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of elritercept in reducing red blood cell (RBC) transfusions

Variables de Evaluación Primaria

Proportion of participants achieving transfusion independence (TI) for 8 weeks from baseline through week 24

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

- 1.To evaluate the efficacy of elritercept in reducing RBC transfusions over longer intervals and/or in participants with high-transfusion burden (HTB)
 - 2.To assess the safety and tolerability of elritercept
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Variables de Evaluación Secundaria

- 1.Proportion of participants achieving TI for 24 weeks from baseline through week 48
 - 2.Proportion of participants with HTB achieving TI for 8 weeks from baseline through week 24
 - 3.Incidence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)
 - 4.Change from baseline in clinical laboratory values, vital signs, and electrocardiograms (ECGs)
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Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information and/or protected personal data in accordance with national and local study participant data protections and privacy regulations.
 2. Male or female 18 years of age at the time of signing informed consent.
 3. Diagnosis of MDS with or without RS (as determined in an evaluable bone marrow aspirate collected at Screening, read by an independent central reader) according to WHO 2016 classification that
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meets the IPSS-R classification of very low, low, or intermediate risk MDS. 4. Transfusion-dependence assessed in the 16 weeks immediately preceding randomization in two 8-week blocks, classified as either: a. LTB, defined as 4 to 7 RBC units per 16 weeks; or b. HTB, defined as 8 RBC units per 16 weeks; and c. For all participants: - Only transfusion events for a pretransfusion Hgb < 10 g/dL are counted toward eligibility; - At least 1 transfusion event in each 8-week period and a minimum of 2 transfusion events separated by 7 days within the 16-week period immediately preceding randomization; and No consecutive 56-day period can be RBC transfusion-free during the 16-week period immediately preceding randomization. 5. Refractory or intolerant to prior ESA treatment (discontinued 4 weeks before randomization), or unlikely to respond to ESA treatment 6. Less than 5% blasts in an evaluable bone marrow aspirate collected at Screening, read by an independent central reader 7. Eastern Cooperative Oncology Group performance status of 0 to 2 8. Females of childbearing potential and sexually active males must agree to use adequate methods

Criterios de Exclusión

1. Del(5q) MDS or therapy-related (secondary) MDS 11. Active infection requiring intravenous treatment (e.g., antibiotics, antifungals, or antivirals) within 28 days, or oral treatment within 14 days before randomization. 12. History of or known active or chronic infection with HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV). Participants without known positive history of HIV, HBV, and/or HCV do not require further testing, unless testing is mandated per local guidelines. 13. Body mass index 40 kg/m² 14. Major surgery within 28 days before randomization 16. Prior use of elritcept, luspatercept, sotatercept. 17. Prior use of hypomethylating agents (HMA), isocitrate dehydrogenase inhibitor, lenalidomide, imetelstat, or immune-suppressive therapy given for treatment of MDS 18. Iron chelation therapy initiated within 8 weeks before randomization. Participants on stable doses of iron chelation therapy for 8 weeks are allowed 19. Vitamin B12 or folate therapy initiated within 4 weeks before randomization. Participants on stable replacement doses for 4 weeks and without concurrent vitamin B12 or folate deficiency are allowed 24. Serum EPO level 500 U/L 25. Platelet count 450 × 10⁹/L or 25 × 10⁹/L 2. Anemia due to any other known cause (e.g., thalassemia, hemolytic anemia, bleeding events, or deficiency of iron, B12, and/or folate). 26. Absolute neutrophil count 500/L 27. Serum aspartate aminotransferase or alanine aminotransferase 3 × the upper limit of normal 28. Total bilirubin 2 × ULN unless attributable to Gilbert's syndrome 29. Ferritin 50 g/L 30. Folate 2.0 ng/mL 31. Vitamin B12 200 pg/mL 32. Estimated glomerular filtration rate < 30 mL/min/1.73m² as determined by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation 33. Pregnant or lactating female 3. Receipt of RBC transfusion for any reason(s) other than underlying MDS within 16 weeks before randomization. 4. Clinically significant cardiovascular disease 5. Known ejection fraction < 35%, confirmed by a local echocardiogram performed during Screening, or other assessment performed echocardiogram if collected within 6 months before Screening 6. Child-Pugh class C hepatic impairment 7. Stroke, deep vein thrombosis, or pulmonary embolism within 6 months before Screening 8. Any known history of AML 9. Prior history of malignancies, other than MDS, unless participant has been free of the disease (including completion of any treatment, including maintenance, for prior malignancy) for 5 years.

Calendario

(Última actualización: 16/04/2026)

Autorización 31/03/2025	Inicio de Ensayo No aportado	Inclusión Primer Paciente 11/07/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (16/06/2025)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology
Activo (27/06/2025)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
Activo (23/06/2025)	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID Hematology
Activo (06/05/2025)	Hospital Universitario Ramon Y Cajal Madrid MADRID Hematology
Activo (23/05/2025)	Hospital Universitario Y Politecnico La Fe Valencia VALENCIA Hematology
Activo (25/02/2026)	Institut Catala D'oncologia L'hospitalet De Llobregat BARCELONA Hematology

Medicamentos

elritercept

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

Principios Activos: N/A

Experimental

Sin resultados

A study of elritercept to treat transfusion-dependent anemia due to very low, low, or intermediate risk myelodysplastic syndromes

State
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase III

Expected Participants
153

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics,
pharmacodynamics, dose

Advanced therapy
NO

Information

Identifier
2024-516009-22-00 (CTIS)

Protocol Code
KER-050-D301

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

Investigated Disease
myelodysplastic neoplasms/syndromes (MDS)

Scientific Title
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Elritercept (KER-050) for the Treatment of Transfusion-Dependent Anemia in Adult Participants with Very Low-, Low-, or Intermediate-Risk Myelodysplastic Syndromes (MDS) (RENEW)

Rationale

Not provided

Main Objective

To evaluate the efficacy of elritercept in reducing red blood cell (RBC) transfusions

Primary Endpoints

Proportion of participants achieving transfusion independence (TI) for 8 weeks from baseline through week 24

Temporary moments of secondary assessment

Not provided

Secondary Objective

- 1.To evaluate the efficacy of elritercept in reducing RBC transfusions over longer intervals and/or in participants with high-transfusion burden (HTB)
 - 2.To assess the safety and tolerability of elritercept
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Secondary Endpoints

- 1.Proportion of participants achieving TI for 24 weeks from baseline through week 48
 - 2.Proportion of participants with HTB achieving TI for 8 weeks from baseline through week 24
 - 3.Incidence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)
 - 4.Change from baseline in clinical laboratory values, vital signs, and electrocardiograms (ECGs)
-

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information and/or protected personal data in accordance with national and local study participant data protections and privacy regulations.
 2. Male or female 18 years of age at the time of signing informed consent.
 3. Diagnosis of MDS with or without RS (as determined in an evaluable bone marrow aspirate collected at Screening, read by an independent central reader) according to WHO 2016 classification that
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meets the IPSS-R classification of very low, low, or intermediate risk MDS. 4. Transfusion-dependence assessed in the 16 weeks immediately preceding randomization in two 8-week blocks, classified as either: a. LTB, defined as 4 to 7 RBC units per 16 weeks; or b. HTB, defined as 8 RBC units per 16 weeks; and c. For all participants: - Only transfusion events for a pretransfusion Hgb < 10 g/dL are counted toward eligibility; - At least 1 transfusion event in each 8-week period and a minimum of 2 transfusion events separated by 7 days within the 16-week period immediately preceding randomization; and No consecutive 56-day period can be RBC transfusion-free during the 16-week period immediately preceding randomization. 5. Refractory or intolerant to prior ESA treatment (discontinued 4 weeks before randomization), or unlikely to respond to ESA treatment 6. Less than 5% blasts in an evaluable bone marrow aspirate collected at Screening, read by an independent central reader 7. Eastern Cooperative Oncology Group performance status of 0 to 2 8. Females of childbearing potential and sexually active males must agree to use adequate methods

Exclusion criteria

1. Del(5q) MDS or therapy-related (secondary) MDS 11. Active infection requiring intravenous treatment (e.g., antibiotics, antifungals, or antivirals) within 28 days, or oral treatment within 14 days before randomization. 12. History of or known active or chronic infection with HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV). Participants without known positive history of HIV, HBV, and/or HCV do not require further testing, unless testing is mandated per local guidelines. 13. Body mass index 40 kg/m² 14. Major surgery within 28 days before randomization 16. Prior use of elritcept, luspatercept, sotatercept. 17. Prior use of hypomethylating agents (HMA), isocitrate dehydrogenase inhibitor, lenalidomide, imetelstat, or immune-suppressive therapy given for treatment of MDS 18. Iron chelation therapy initiated within 8 weeks before randomization. Participants on stable doses of iron chelation therapy for 8 weeks are allowed 19. Vitamin B12 or folate therapy initiated within 4 weeks before randomization. Participants on stable replacement doses for 4 weeks and without concurrent vitamin B12 or folate deficiency are allowed 24. Serum EPO level 500 U/L 25. Platelet count 450 × 10⁹/L or 25 × 10⁹/L 2. Anemia due to any other known cause (e.g., thalassemia, hemolytic anemia, bleeding events, or deficiency of iron, B12, and/or folate). 26. Absolute neutrophil count 500/L 27. Serum aspartate aminotransferase or alanine aminotransferase 3 × the upper limit of normal 28. Total bilirubin 2 × ULN unless attributable to Gilbert's syndrome 29. Ferritin 50 g/L 30. Folate 2.0 ng/mL 31. Vitamin B12 200 pg/mL 32. Estimated glomerular filtration rate < 30 mL/min/1.73m² as determined by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation 33. Pregnant or lactating female 3. Receipt of RBC transfusion for any reason(s) other than underlying MDS within 16 weeks before randomization. 4. Clinically significant cardiovascular disease 5. Known ejection fraction < 35%, confirmed by a local echocardiogram performed during Screening, or other assessment performed echocardiogram if collected within 6 months before Screening 6. Child-Pugh class C hepatic impairment 7. Stroke, deep vein thrombosis, or pulmonary embolism within 6 months before Screening 8. Any known history of AML 9. Prior history of malignancies, other than MDS, unless participant has been free of the disease (including completion of any treatment, including maintenance, for prior malignancy) for 5 years.

Calendar

(Last Update: 16/04/2026)

Authorization 31/03/2025	Start of Trial Not aported	First patient inclusion 11/07/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

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Monetary support: N/A
Sponsor type: Commercial

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Medication

elritercept

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

Active Principles: N/A

Experimental

No results