A Phase III, Open-label, Single Arm, Prospective, Multicenter Study to Assess Efficacy and Safety of Kedrion Intravenous Human Normal Immunoglobulin (IVIg) 10% in Adult Patients with Chronic Immune Thrombocytopenia (ITP)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	16
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, dosis	NO

Información

Identificador
2023-507115-35-00 (CTIS)

Cod. Protocolo
KB072

Área terapéutica
Enfermedades [C] - Patologías del sistema inmunitario [C20]|

Enfermedad investigada
Chronic Immune Thrombocytopenia (ITP)

Título Científico
A Phase III, Open-label, Single Arm, Prospective, Multicenter Study to Assess Efficacy and Safety of Kedrion Intravenous Human Normal Immunoglobulin (IVIg) 10% in Adult Patients with Chronic Immune Thrombocytopenia (ITP)

Justificación

No aportado

Objetivo Principal

To assess the responder rate of KIg10 in the treatment of adults with chronic ITP by measuring platelet count increase according to the Response (R) definition

Variables de Evaluación Primaria

The rate of participants with response (R), defined as participants with a platelet count > 30 × 109/L and at least a 2-fold increase of the baseline count, confirmed during the evaluation period on at least 2 separate occasions at least 7 days apart, and absence of bleeding during the evaluation period.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the clinical response rate of KIg10 platelet count increase and absence of bleeding according to the Complete Response (CR), Loss of R/CR, Nonresponders definitions.
To assess the time to platelet count response.
To assess the duration of response.
To assess the time to stop bleeding.
To assess the maximum platelet count.
To assess time to achieve maximum platelet count.
To assess the reduction of bleeding symptoms

Variables de Evaluación Secundaria

1.Number and rate of participants with: a.CR: PLT > 100x109/L on 2 occasions at least 7 days apart and no bleeding b. loss of CR or R: PLT <100x109/L or bleeding (CR) or PLT <30x109/L or < 2-fold increase of baseline or bleeding (R) c.Nonresponders (NR) 2.Time to response 3. Response Duration 4. Hemorrhages regression of 5. maximum PLT count achieved 6.Time to maximum PLT count 7.Bleedings (timing/grade)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male or female, 18-70 years of age. 2. Patient and/or legal authorized representative has signed the ICF. 3. Diagnosis of chronic (> 12 months duration) ITP as defined by the International Working Group. 4. Mean screening platelet count of < 30 × 109/L from two qualifying counts measured at least one calendar day apart. The first qualifying count can be from historical data if measured within 7 days prior to the screening. The second qualifying count will be measured within 7 days before the first KIg10 infusion. 5. Platelet count of < 30 × 109/L at the Baseline Visit. 6. Patient is willing to comply with all requirements of the protocol. 7. Women of childbearing potential must have a negative urine pregnancy test at screening and agree to employ adequate birth control measures during the study. 8. Authorization to access personal health information.

Criterios de Exclusión

1. Patients with secondary ITP 18. Signs of severe anemia 19. BMI > 40 kg/m2 or an IVIg dose that puts the patient at risk of fluid overload 2. Patients with Evans Syndrome, inherited thrombocytopenia, myelodysplastic syndrome 20. History of a malignant disease within 3 years of the Baseline Visit other than treated carcinoma in situ of the cervix or basal cell or squamous cell carcinoma of the skin 21. Patient has participated in an interventional, investigational clinical study within 30 days of the Baseline Visit 3. Patients infected with HBV, HCV or HIV 4. Patients with a history of thrombotic events and/or at high risk of thrombotic events 5. History of hypersensitivity to IVIg or to any of the excipients 6. Patients unresponsive previously to IVIg or anti-D Ig treatment 7. Patients with immunoglobulin A deficiency and Ab against IgA 10. Received platelets within 7days of Visit 1 and any other blood/plasma product within 1 month of the Baseline Visit (BV) 8. Splenectomy within 4 weeks of the Baseline Visit or planned throughout the study 9. Administration of IVIg, anti-D Ig, Mercaptopurine, Vinca alkaloid, or platelet enhancing drugs within 3 weeks of the Baseline Visit unless patients are on stable treatment as defined. Treatment with any other products licensed for primary chronic ITP is also exclusive. 11. Received recombinant activated factor VII within 7 days rituximab within 6 months of the BV 12 Received live attenuated virus vaccines within 3 months of the BV 13. Use of loop diuretics w/i 1 week of the BV 14. Uncontrolled hypertension 15. Congestive heart failure as per New York Heart Association III/IV, cardiomyopathy, cardiac arrhythmia associated with thromboembolic events , unstable or advanced ischemic heart disease, hyperviscosity 16. Patients with significant protein losing enteropathy, nephrotic syndrome, lymphangiectasia, hyperproteinemia, increased serum viscosity and/or hyponatremia 17. Severe liver or kidney disease

Calendario

(Última actualización: 04/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
30/04/2025	16/02/2026	16/02/2026	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Kedrion S.p.A. Italy

Castelvecchio PascoliLocalita Ai Conti Snc

Contact Person

Miranda Norton

+447920143127

m.norton@kedrion.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Centros

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

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Haematology Service

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Haematology Service

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

Hospital Ruber Juan Bravo

Madrid

MADRID

Haematology Service

Medicamentos

KIg10
SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

Sin resultados

A Phase III, Open-label, Single Arm, Prospective, Multicenter Study to Assess Efficacy and Safety of Kedrion Intravenous Human Normal Immunoglobulin (IVIg) 10% in Adult Patients with Chronic Immune Thrombocytopenia (ITP)

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	16
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, dose	NO

Information

Identifier
2023-507115-35-00 (CTIS)

Protocol Code
KB072

Therapeutic area
Diseases [C] - Immune System Diseases [C20]|

Investigated Disease
Chronic Immune Thrombocytopenia (ITP)

Scientific Title
A Phase III, Open-label, Single Arm, Prospective, Multicenter Study to Assess Efficacy and Safety of Kedrion Intravenous Human Normal Immunoglobulin (IVIg) 10% in Adult Patients with Chronic Immune Thrombocytopenia (ITP)

Rationale

Not provided

Main Objective

To assess the responder rate of KIg10 in the treatment of adults with chronic ITP by measuring platelet count increase according to the Response (R) definition

Primary Endpoints

The rate of participants with response (R), defined as participants with a platelet count > 30 × 109/L and at least a 2-fold increase of the baseline count, confirmed during the evaluation period on at least 2 separate occasions at least 7 days apart, and absence of bleeding during the evaluation period.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the clinical response rate of KIg10 platelet count increase and absence of bleeding according to the Complete Response (CR), Loss of R/CR, Nonresponders definitions.
To assess the time to platelet count response.
To assess the duration of response.
To assess the time to stop bleeding.
To assess the maximum platelet count.
To assess time to achieve maximum platelet count.
To assess the reduction of bleeding symptoms

Secondary Endpoints

1.Number and rate of participants with: a.CR: PLT > 100x109/L on 2 occasions at least 7 days apart and no bleeding b. loss of CR or R: PLT <100x109/L or bleeding (CR) or PLT <30x109/L or < 2-fold increase of baseline or bleeding (R) c.Nonresponders (NR) 2.Time to response 3. Response Duration 4. Hemorrhages regression of 5. maximum PLT count achieved 6.Time to maximum PLT count 7.Bleedings (timing/grade)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male or female, 18-70 years of age. 2. Patient and/or legal authorized representative has signed the ICF. 3. Diagnosis of chronic (> 12 months duration) ITP as defined by the International Working Group. 4. Mean screening platelet count of < 30 × 109/L from two qualifying counts measured at least one calendar day apart. The first qualifying count can be from historical data if measured within 7 days prior to the screening. The second qualifying count will be measured within 7 days before the first KIg10 infusion. 5. Platelet count of < 30 × 109/L at the Baseline Visit. 6. Patient is willing to comply with all requirements of the protocol. 7. Women of childbearing potential must have a negative urine pregnancy test at screening and agree to employ adequate birth control measures during the study. 8. Authorization to access personal health information.

Exclusion criteria

1. Patients with secondary ITP 18. Signs of severe anemia 19. BMI > 40 kg/m2 or an IVIg dose that puts the patient at risk of fluid overload 2. Patients with Evans Syndrome, inherited thrombocytopenia, myelodysplastic syndrome 20. History of a malignant disease within 3 years of the Baseline Visit other than treated carcinoma in situ of the cervix or basal cell or squamous cell carcinoma of the skin 21. Patient has participated in an interventional, investigational clinical study within 30 days of the Baseline Visit 3. Patients infected with HBV, HCV or HIV 4. Patients with a history of thrombotic events and/or at high risk of thrombotic events 5. History of hypersensitivity to IVIg or to any of the excipients 6. Patients unresponsive previously to IVIg or anti-D Ig treatment 7. Patients with immunoglobulin A deficiency and Ab against IgA 10. Received platelets within 7days of Visit 1 and any other blood/plasma product within 1 month of the Baseline Visit (BV) 8. Splenectomy within 4 weeks of the Baseline Visit or planned throughout the study 9. Administration of IVIg, anti-D Ig, Mercaptopurine, Vinca alkaloid, or platelet enhancing drugs within 3 weeks of the Baseline Visit unless patients are on stable treatment as defined. Treatment with any other products licensed for primary chronic ITP is also exclusive. 11. Received recombinant activated factor VII within 7 days rituximab within 6 months of the BV 12 Received live attenuated virus vaccines within 3 months of the BV 13. Use of loop diuretics w/i 1 week of the BV 14. Uncontrolled hypertension 15. Congestive heart failure as per New York Heart Association III/IV, cardiomyopathy, cardiac arrhythmia associated with thromboembolic events , unstable or advanced ischemic heart disease, hyperviscosity 16. Patients with significant protein losing enteropathy, nephrotic syndrome, lymphangiectasia, hyperproteinemia, increased serum viscosity and/or hyponatremia 17. Severe liver or kidney disease

Calendar

(Last Update: 04/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
30/04/2025	16/02/2026	16/02/2026	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Kedrion S.p.A. Italy

Castelvecchio PascoliLocalita Ai Conti Snc

Contact Person

Miranda Norton

+447920143127

m.norton@kedrion.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Sites

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

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Haematology Service

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Haematology Service

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

Hospital Ruber Juan Bravo

Madrid

MADRID

Haematology Service

Medication

KIg10
SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

No results