Clinical study in order to compare the effectiveness and safety of two different treatments in patients with newly diagnosed primary immune thrombocytopenia

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	126
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-514147-28-00 (CTIS)

Cod. Protocolo
RODEX

Transicionado 2021-006970-22

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

Enfermedad investigada
Primary immune thrombocytopenia

Título Científico
A multicentre, randomized, open-label study of romiplostim plus dexamethasone vs dexamethasone in patients with newly diagnosed primary immune thrombocytopenia

Justificación

No aportado

Objetivo Principal

To evaluate the superiority of romiplostim plus dexamethasone versus dexamethasone alone after 6 months (180 days) from treatment cessation in patients with newly diagnosed primary immune thrombocytopenia (ITP) in terms of sustained response off any ITP treatment (6mSROT-50) and without WHO grade 2 or more bleeding.

Variables de Evaluación Primaria

To evaluate the difference between study arms in the proportion of patients achieving 6mSROT-50 at 6 months (180 days) from treatment cessation. Definition of 6mSROT-50: platelets higher or equal than 50x109/L in the absence of any ITP treatment including any rescue treatment for at least 6 consecutive months (180 days) from treatment cessation and without WHO grade 2 or more bleeding.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

- To evaluate the difference between study arms in the proportion of patients with newly diagnosed of ITP achieving platelets >= than 30x109/L (SROT-30) or 50 x109/L (SROT-50) in the absence of any ITP treatment including any rescue treatment for at least 6 consecutive months (180 days) or 12 consecutive months from treatment cessation and without WHO grade 2 or more bleeding. - To evaluate the difference between study arms in the proportion of patients with newly diagnosed of ITP with complete response, response, global response and targeted range. Also with early response and initial response - To compare the time to loss of response(LoR)in patients who achieved response in both arms. - To compare the difference between study arms in the proportion of patients requiring any rescue treatment along the study period. - To compare the difference between study arms in the proportion of patients with adverse events, including serious adverse events and laboratory safety parameters.

Variables de Evaluación Secundaria

-To evaluate the difference between study arms in the proportion of patients achieving 6mSROT-30 at 6 months (180 days) from treatment cessation. -To evaluate the difference between study arms in the proportion of patients achieving 12mSROT-50 at 12 months (365 days) from treatment cessation. -To evaluate the difference between study arms in the proportion of patients achieving 12mSROT-30 at 12 months (365 days) from treatment cessation

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1.Age 18 years of age at the time of signing informed consent. 2.Newly diagnosis of primary ITP according to the International Working Group assessment [1] and previously untreated for ITP. 3.Platelet counts <30x109/L or ITP with platelet counts <50x109/L and concomitant bleeding symptoms. 4.Serum creatinine concentration 1.5 mg/dL.

Criterios de Exclusión

1.WHO performance status >2. 2.Previous therapy with rituximab (within 3 months previous of study enrollment), corticosteroids, therapy with other immunomodulating agents within 1 month of enrolment, hematopoietic analogs and fostamatinib for any other reason than ITP. 3.Previous use of romiplostim, PEG-recombinant human (rHu) megakaryocyte growth and development factor, eltrombopag, recombinant human anti-thrombopoietin (rHuTPO), or any plateletproducing agent for three months prior to enrolment. 4.Alkylating agents within 8 weeks before the screening visit or anticipated use during the time of the proposed study. 5.Splenectomy within 3 months of the screening visit or planned splenectomy during study period. 6.Abnormal renal function (serum creatinine > 1.5 mg/dL). 7.Active hepatic disease (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] levels >5 times the upper limit of normal). 8.Severe chronic liver disease as evidenced by, but not limited to, any of the following: International Normalized Ratio (INR) > 1.4, hypoalbuminemia, portal vein hypertension including presence of otherwise unexplained splenomegaly and history of esophageal varices. 9.Pregnancy or lactation. 10.Patients with known IgM seropositive tests for cytomegalovirus and/or Epstein-Barr virus in the previous month. 11.Patients with known serum-positivity and a positive test for an active viral infection at screening with: Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), detectable virus charge of HIV. 12.Intolerance to dexamethasone or romiplostim. 13.History of a bone marrow stem cell disorder. 14.Active or prior malignancy except adequately treated (ie, complete surgical excision with negative margins) basal cell carcinoma in the last 5 years.. 15.History of Heliobacter pylori by urea breath test or stool antigen test within 6 months of enrollment, if available. 16.History of myelodysplastic syndrome, systemic lupus erythematosus, or autoimmune cytopenia. 17.History of antiphospholipid antibody syndrome. 18.History of disseminated intravascular coagulation, hemolytic uremic syndrome, or thrombotic thrombocytopenic purpura. 19.History of deep or superficial venous thromboembolism in the last 12 months or stroke, acute ischaemic heart disease or acute peripheral vascular disese in the last 6 months. 20.Hypersensitivity to any recombinant Escherichia coli-derived product (eg, Infergen, Neupogen, Somatropin, and Actimmune) or known sensitivity to any of the products to be administered during dosing 21.Currently enrolled in another investigational device or drug study or < 30 days since ending another investigational device or drug studies, or receiving other investigational agents. 22.Will have any other investigational procedures performed while enrolled in this clinical study. 23.Pregnant or breastfeeding, or planning to become pregnant or breastfeed during treatment or within 1 month after the end of treatment. 24.Female subject of childbearing potential is not willing to use, in combination with her partner, an acceptable method of effective contraception during treatment and for 1 month after the end of treatment (see annex 5 for additional contraception information). Females of childbearing potential should only be included after a negative, highly sensitive urine pregnancy test. 25.Will not be available for protocol-required study visits, to the best of the subject's and investigator's knowledge. 26.Any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent and/or to comply with all required study procedures. 27.Other serious comorbidities at investigator criteria.

Calendario

(Última actualización: 13/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/08/2022	01/12/2022	02/12/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
30/04/2025	No aportado	No aportado	No aportado	No aportado

Promotor

Fundacion Publica Andaluza Para La Gestion De La Investigacion En Salud De Sevilla Spain

Avenida De Manuel Siurot Sn

Contact Person

Clinical Trial Unit IBIS/University Hospital Virgen del Rocío

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Monetary support: N/A

Tipo de promotor: No comercial

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955043127

Centros

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CENTRE SOCIOSANITARI SANT JORDI DE LA VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología y Hemoterapia

Activo (26/01/2023)

COMPLEJO ASISTENCIAL SON ESPASES (*)

Palma

BALEARES

Servicio de Hematología y Hemoterapia

Activo (15/12/2022)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE BURGOS

Burgos

BURGOS

Servicio de Hematología y Hemoterapia

Activo (09/02/2023)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematología

Activo (23/02/2023)

Complejo Hospitalario La Paz

Madrid

MADRID

Servicio de Hematología y Hemoterapia

Activo (17/01/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA

Coruña, A

CORUÑA

Servicio de Hematología y Hemoterapia

Activo (13/12/2022)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Servicio de Hematología y Hemoterapia

Activo (12/01/2023)

HOSPITAL DEL MAR.

Barcelona

BARCELONA

Servicio de Hematología y Hemoterapia

Activo (18/01/2023)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Servicio de Hematología y Hemoterapia

Activo (23/02/2023)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Servicio Hematología y Hemoterapia

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

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

Activo (14/12/2022)

HOSPITAL UNIVERSITARIO FUNDACION ALCORCON

Alcorcón

MADRID

Unidad de Hematología y Hemoterapia

Activo (15/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN DE LA VICTORIA

Málaga

MÁLAGA

UGC Hematología y Hemoterapia

Activo (13/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

Unidad Hematología y Hemoterapia

Activo (01/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Haematology Department

Activo (21/02/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Servicio de Hematología y Hemoterapia

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

University Hospital Son Espases

Palma

BALEARES

Hematology

Medicamentos

Nplate 250 micrograms powder for solution for injection

POWDER FOR INJECTION

SUBCUTANEOUS USE

Código ATC: B02BX04 - ROMIPLOSTIM

Principios Activos: N/A

Experimental

Nplate 500 micrograms powder and solvent for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

Código ATC: B02BX04 - ROMIPLOSTIM

Principios Activos: N/A

Experimental

-

-

ORAL

Código ATC: S01BA01 - DEXAMETASONA

Principios Activos: N/A

Experimental

Sin resultados

Clinical study in order to compare the effectiveness and safety of two different treatments in patients with newly diagnosed primary immune thrombocytopenia

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	126
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	treatment, safety, effectiveness	NO

Information

Identifier
2024-514147-28-00 (CTIS)

Protocol Code
RODEX

Transitioned 2021-006970-22

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

Investigated Disease
Primary immune thrombocytopenia

Scientific Title
A multicentre, randomized, open-label study of romiplostim plus dexamethasone vs dexamethasone in patients with newly diagnosed primary immune thrombocytopenia

Rationale

Not provided

Main Objective

To evaluate the superiority of romiplostim plus dexamethasone versus dexamethasone alone after 6 months (180 days) from treatment cessation in patients with newly diagnosed primary immune thrombocytopenia (ITP) in terms of sustained response off any ITP treatment (6mSROT-50) and without WHO grade 2 or more bleeding.

Primary Endpoints

To evaluate the difference between study arms in the proportion of patients achieving 6mSROT-50 at 6 months (180 days) from treatment cessation. Definition of 6mSROT-50: platelets higher or equal than 50x109/L in the absence of any ITP treatment including any rescue treatment for at least 6 consecutive months (180 days) from treatment cessation and without WHO grade 2 or more bleeding.

Temporary moments of secondary assessment

Not provided

Secondary Objective

- To evaluate the difference between study arms in the proportion of patients with newly diagnosed of ITP achieving platelets >= than 30x109/L (SROT-30) or 50 x109/L (SROT-50) in the absence of any ITP treatment including any rescue treatment for at least 6 consecutive months (180 days) or 12 consecutive months from treatment cessation and without WHO grade 2 or more bleeding. - To evaluate the difference between study arms in the proportion of patients with newly diagnosed of ITP with complete response, response, global response and targeted range. Also with early response and initial response - To compare the time to loss of response(LoR)in patients who achieved response in both arms. - To compare the difference between study arms in the proportion of patients requiring any rescue treatment along the study period. - To compare the difference between study arms in the proportion of patients with adverse events, including serious adverse events and laboratory safety parameters.

Secondary Endpoints

-To evaluate the difference between study arms in the proportion of patients achieving 6mSROT-30 at 6 months (180 days) from treatment cessation. -To evaluate the difference between study arms in the proportion of patients achieving 12mSROT-50 at 12 months (365 days) from treatment cessation. -To evaluate the difference between study arms in the proportion of patients achieving 12mSROT-30 at 12 months (365 days) from treatment cessation

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1.Age 18 years of age at the time of signing informed consent. 2.Newly diagnosis of primary ITP according to the International Working Group assessment [1] and previously untreated for ITP. 3.Platelet counts <30x109/L or ITP with platelet counts <50x109/L and concomitant bleeding symptoms. 4.Serum creatinine concentration 1.5 mg/dL.

Exclusion criteria

1.WHO performance status >2. 2.Previous therapy with rituximab (within 3 months previous of study enrollment), corticosteroids, therapy with other immunomodulating agents within 1 month of enrolment, hematopoietic analogs and fostamatinib for any other reason than ITP. 3.Previous use of romiplostim, PEG-recombinant human (rHu) megakaryocyte growth and development factor, eltrombopag, recombinant human anti-thrombopoietin (rHuTPO), or any plateletproducing agent for three months prior to enrolment. 4.Alkylating agents within 8 weeks before the screening visit or anticipated use during the time of the proposed study. 5.Splenectomy within 3 months of the screening visit or planned splenectomy during study period. 6.Abnormal renal function (serum creatinine > 1.5 mg/dL). 7.Active hepatic disease (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] levels >5 times the upper limit of normal). 8.Severe chronic liver disease as evidenced by, but not limited to, any of the following: International Normalized Ratio (INR) > 1.4, hypoalbuminemia, portal vein hypertension including presence of otherwise unexplained splenomegaly and history of esophageal varices. 9.Pregnancy or lactation. 10.Patients with known IgM seropositive tests for cytomegalovirus and/or Epstein-Barr virus in the previous month. 11.Patients with known serum-positivity and a positive test for an active viral infection at screening with: Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), detectable virus charge of HIV. 12.Intolerance to dexamethasone or romiplostim. 13.History of a bone marrow stem cell disorder. 14.Active or prior malignancy except adequately treated (ie, complete surgical excision with negative margins) basal cell carcinoma in the last 5 years.. 15.History of Heliobacter pylori by urea breath test or stool antigen test within 6 months of enrollment, if available. 16.History of myelodysplastic syndrome, systemic lupus erythematosus, or autoimmune cytopenia. 17.History of antiphospholipid antibody syndrome. 18.History of disseminated intravascular coagulation, hemolytic uremic syndrome, or thrombotic thrombocytopenic purpura. 19.History of deep or superficial venous thromboembolism in the last 12 months or stroke, acute ischaemic heart disease or acute peripheral vascular disese in the last 6 months. 20.Hypersensitivity to any recombinant Escherichia coli-derived product (eg, Infergen, Neupogen, Somatropin, and Actimmune) or known sensitivity to any of the products to be administered during dosing 21.Currently enrolled in another investigational device or drug study or < 30 days since ending another investigational device or drug studies, or receiving other investigational agents. 22.Will have any other investigational procedures performed while enrolled in this clinical study. 23.Pregnant or breastfeeding, or planning to become pregnant or breastfeed during treatment or within 1 month after the end of treatment. 24.Female subject of childbearing potential is not willing to use, in combination with her partner, an acceptable method of effective contraception during treatment and for 1 month after the end of treatment (see annex 5 for additional contraception information). Females of childbearing potential should only be included after a negative, highly sensitive urine pregnancy test. 25.Will not be available for protocol-required study visits, to the best of the subject's and investigator's knowledge. 26.Any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent and/or to comply with all required study procedures. 27.Other serious comorbidities at investigator criteria.

Calendar

(Last Update: 13/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/08/2022	01/12/2022	02/12/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
30/04/2025	Not aported	Not aported	Not aported	Not aported

Sponsor

Fundacion Publica Andaluza Para La Gestion De La Investigacion En Salud De Sevilla Spain

Avenida De Manuel Siurot Sn

Contact Person

Clinical Trial Unit IBIS/University Hospital Virgen del Rocío

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Monetary support: N/A

Sponsor type: No commercial

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Sites

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Servicio de Hematología y Hemoterapia

Active (26/01/2023)

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

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València

VALENCIA

Servicio de Hematología y Hemoterapia

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

University Hospital Son Espases

Palma

BALEARES

Hematology

Medication

Nplate 250 micrograms powder for solution for injection

POWDER FOR INJECTION

SUBCUTANEOUS USE

ATC code: B02BX04 - ROMIPLOSTIM

Active Principles: N/A

Experimental

Nplate 500 micrograms powder and solvent for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: B02BX04 - ROMIPLOSTIM

Active Principles: N/A

Experimental

-

-

ORAL

ATC code: S01BA01 - DEXAMETASONA

Active Principles: N/A

Experimental

No results