Double-blind (neither the patient nor the doctor knows treatment allocation of the patient), randomized, placebo-controlled, prospective phase III clinical study to evaluate the efficacy and safety of Panzyga in infection prevention in patients with a specific type of cancer, cancer of the blood and bone marrow (Chronic Lymphocytic Leukemia) ("PRO-SID" study).

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	240
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	profilaxis, seguridad, eficacia, farmacocinética, farmacoeconómica	NO

Información

Identificador
2023-509737-39-00 (CTIS)

Cod. Protocolo
NGAM-12

Transicionado 2019-004375-40

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Primary infection prophylaxis in patients with chronic lymphocytic leukemia (CLL) and secondary hypogammaglobulinemia.

Título Científico

Double-blind, Randomized, Placebo-controlled, Prospective Phase III Study Evaluating Efficacy and Safety of Panzyga in Primary Infection Prophylaxis in Patients with Chronic Lymphocytic Leukemia (PRO-SID study).

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to demonstrate the benefit of Panzyga administration compared with placebo as primary infection prophylaxis in CLL patients with secondary
immunodeficiency (SID) undergoing CLL antineoplastic therapy.

Variables de Evaluación Primaria

Since the study objective is to show the benefit of Panzyga administration as primary infection prophylaxis, the primary endpoint is not the major infection rate but occurrence of at least one major infection in CLL patients with or without primary infection prophylaxis with Panzyga. Please refer to the Protocol for more information on the Primary endpoint.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary objectives of this study are to compare the following aspects in CLL patients with SID treated with and without primary Panzyga prophylaxis: - Overall infection rate - Frequency of prophylaxis with anti-infectives (antibacterials and antivirals) - Duration of prophylaxis with anti-infectives (antibacterials and antivirals)

Variables de Evaluación Secundaria

1. Overall infection rate: infection rate for all infections.
2. Frequency of prophylaxis with anti-infectives (antibacterials and antivirals).
3. Duration of prophylaxis with anti-infectives (antibacterials and antivirals).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Treatment-naïve or relapsed/refractory CLL patients undergoing CLL antineoplastic treatment. Diagnosis of B-cell CLL established according to International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria and documented within medical records. 2. Hypogammaglobulinemia (IgG levels <5 g/L) as confirmed by the Central Laboratory. 3. 18 years of age. 4. Voluntarily given, fully informed written and signed consent obtained before any study-related procedures are conducted.

Criterios de Exclusión

1. IgG treatment within 3 months prior to Screening. 6. Severe liver disease, with signs of ascites and/or hepatic encephalopathy. 7. Severe kidney disease (as defined by estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m 2). 8. Body weight >140 kg. 9. Eastern Cooperative Oncology Group (ECOG) performance score of >2 (Appendix1). 14. Pregnant and lactating women. 15. Subjects with a history of thromboembolic events (TEE) such as deep vein thrombosis, pulmonary embolism, myocardial infarction, ischemic stroke, transient ischemic attack, peripheral artery disease (Fontaine IV) within 6 months before Baseline. 16. Planned or ongoing immunosuppressive treatment (other than for CLL or corticosteroids) or other forbidden medication during the entire study duration after study enrollment. 17. Participation in another interventional clinical trial that is either blinded or involves an investigational (not approved) product within 3 months before Baseline or during the course of the clinical study. Participation in observational clinical trials or open-label trials involving an approved product may be permitted after consultation with the medical monitor. 18. Known IgA deficiency with antibodies to IgA (as part of the patient´s medical history). 19. Known blood hyperviscosity, or other hypercoagulable states. 10. Female patients of childbearing potential unwilling to use a protocol-required method of contraception (as per protocol section 7.3.9 b) from the Screening Visit throughout the study treatment period and for 30 days following the last dose of study drug. 20. Patients unable or unwilling to understand or comply with the study protocol. 11. Human immunodeficiency virus (HIV) infection at Screening (defined for the study as positive HIV antibody test). 12. Patients found to be chronic carriers of hepatitis B virus (HBV), defined by positive surface antigen (HBsAg), positive Hepatitis B core antibodies (HBcAb) and/or low HBV titers, who will not receive targeted antiviral therapy while undergoing CLL therapy, and patients with active HBV, defined as high HBV titers. 13. Uncontrolled hepatitis C infection at Screening (defined for the study as positive hepatitis virus C (HCV) polymerase chain reaction (PCR)). 2. Antibiotic prophylaxis and/or treatment within 7 days prior to Baseline (with the exception of trimethoprim-sulfamethoxazole (TMP/SMX), diaminodiphenyl sulfone [dapsone] and pentamidine inhalation). 3. Current major infection or >1 major infection in the previous 6 months before Baseline. 4. History of anaphylaxis or severe systemic response to immunoglobulin, blood or plasma-derived products or any Panzyga component. 5. History of a non-CLL malignancy or other medical condition with life-expectancy of less than two years.

Calendario

(Última actualización: 12/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/03/2023	20/07/2023	21/08/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
27/08/2024	No aportado	No aportado	07/01/2025	20/09/2025

Promotor

Octapharma Pharmazeutika Produktionsgesellschaft mbH Austria

Oberlaaer Strasse 235Favoriten

Contact Person

Global Clinical Project Manager

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

No iniciado (27/03/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Medicamentos

Panzyga 100 mg/ml Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

Tiene resultados

Double-blind (neither the patient nor the doctor knows treatment allocation of the patient), randomized, placebo-controlled, prospective phase III clinical study to evaluate the efficacy and safety of Panzyga in infection prevention in patients with a specific type of cancer, cancer of the blood and bone marrow (Chronic Lymphocytic Leukemia) ("PRO-SID" study).

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	240
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	prophylaxis, safety, effectiveness, pharmacokinetics, pharmacoeconomic	NO

Information

Identifier
2023-509737-39-00 (CTIS)

Protocol Code
NGAM-12

Transitioned 2019-004375-40

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Primary infection prophylaxis in patients with chronic lymphocytic leukemia (CLL) and secondary hypogammaglobulinemia.

Scientific Title

Double-blind, Randomized, Placebo-controlled, Prospective Phase III Study Evaluating Efficacy and Safety of Panzyga in Primary Infection Prophylaxis in Patients with Chronic Lymphocytic Leukemia (PRO-SID study).

Rationale

Not provided

Main Objective

The primary objective of this study is to demonstrate the benefit of Panzyga administration compared with placebo as primary infection prophylaxis in CLL patients with secondary
immunodeficiency (SID) undergoing CLL antineoplastic therapy.

Primary Endpoints

Since the study objective is to show the benefit of Panzyga administration as primary infection prophylaxis, the primary endpoint is not the major infection rate but occurrence of at least one major infection in CLL patients with or without primary infection prophylaxis with Panzyga. Please refer to the Protocol for more information on the Primary endpoint.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary objectives of this study are to compare the following aspects in CLL patients with SID treated with and without primary Panzyga prophylaxis: - Overall infection rate - Frequency of prophylaxis with anti-infectives (antibacterials and antivirals) - Duration of prophylaxis with anti-infectives (antibacterials and antivirals)

Secondary Endpoints

1. Overall infection rate: infection rate for all infections.
2. Frequency of prophylaxis with anti-infectives (antibacterials and antivirals).
3. Duration of prophylaxis with anti-infectives (antibacterials and antivirals).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Treatment-naïve or relapsed/refractory CLL patients undergoing CLL antineoplastic treatment. Diagnosis of B-cell CLL established according to International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria and documented within medical records. 2. Hypogammaglobulinemia (IgG levels <5 g/L) as confirmed by the Central Laboratory. 3. 18 years of age. 4. Voluntarily given, fully informed written and signed consent obtained before any study-related procedures are conducted.

Exclusion criteria

1. IgG treatment within 3 months prior to Screening. 6. Severe liver disease, with signs of ascites and/or hepatic encephalopathy. 7. Severe kidney disease (as defined by estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m 2). 8. Body weight >140 kg. 9. Eastern Cooperative Oncology Group (ECOG) performance score of >2 (Appendix1). 14. Pregnant and lactating women. 15. Subjects with a history of thromboembolic events (TEE) such as deep vein thrombosis, pulmonary embolism, myocardial infarction, ischemic stroke, transient ischemic attack, peripheral artery disease (Fontaine IV) within 6 months before Baseline. 16. Planned or ongoing immunosuppressive treatment (other than for CLL or corticosteroids) or other forbidden medication during the entire study duration after study enrollment. 17. Participation in another interventional clinical trial that is either blinded or involves an investigational (not approved) product within 3 months before Baseline or during the course of the clinical study. Participation in observational clinical trials or open-label trials involving an approved product may be permitted after consultation with the medical monitor. 18. Known IgA deficiency with antibodies to IgA (as part of the patient´s medical history). 19. Known blood hyperviscosity, or other hypercoagulable states. 10. Female patients of childbearing potential unwilling to use a protocol-required method of contraception (as per protocol section 7.3.9 b) from the Screening Visit throughout the study treatment period and for 30 days following the last dose of study drug. 20. Patients unable or unwilling to understand or comply with the study protocol. 11. Human immunodeficiency virus (HIV) infection at Screening (defined for the study as positive HIV antibody test). 12. Patients found to be chronic carriers of hepatitis B virus (HBV), defined by positive surface antigen (HBsAg), positive Hepatitis B core antibodies (HBcAb) and/or low HBV titers, who will not receive targeted antiviral therapy while undergoing CLL therapy, and patients with active HBV, defined as high HBV titers. 13. Uncontrolled hepatitis C infection at Screening (defined for the study as positive hepatitis virus C (HCV) polymerase chain reaction (PCR)). 2. Antibiotic prophylaxis and/or treatment within 7 days prior to Baseline (with the exception of trimethoprim-sulfamethoxazole (TMP/SMX), diaminodiphenyl sulfone [dapsone] and pentamidine inhalation). 3. Current major infection or >1 major infection in the previous 6 months before Baseline. 4. History of anaphylaxis or severe systemic response to immunoglobulin, blood or plasma-derived products or any Panzyga component. 5. History of a non-CLL malignancy or other medical condition with life-expectancy of less than two years.

Calendar

(Last Update: 12/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/03/2023	20/07/2023	21/08/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
27/08/2024	Not aported	Not aported	07/01/2025	20/09/2025

Sponsor

Octapharma Pharmazeutika Produktionsgesellschaft mbH Austria

Oberlaaer Strasse 235Favoriten

Contact Person

Global Clinical Project Manager

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Monetary support: N/A

Sponsor type: Commercial

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Sites

not initialized (27/03/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Medication

Panzyga 100 mg/ml Infusionslösung

SOLUTION FOR INFUSION

INTRAVENOUS

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

Has results