Multi-cohort Study to Customize Ibrutinib Treatment Regimens for Patients with Previously Untreated Chronic Lymphocytic Leukemia TAILOR

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	122
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-504044-34-00 (CTIS)

Cod. Protocolo
54179060CLL2032

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

Enfermedad investigada
Untreated Chronic Lymphocytic Leukemia

Título Científico
Multicohort Study to Customize Ibrutinib Treatment Regimens for Patients with Previously Untreated Chronic Lymphocytic Leukemia

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of I+V and ibrutinib monotherapy regimens using a tailored treatment approach in which dosing of ibrutinib is either proactively reduced or reactively modified (per the label) in response to AEs, compared with clinical trial-based historical controls of ibrutinib monotherapy and I+V

Variables de Evaluación Primaria

Best ORR by investigator assessment

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

2. Diagnosis of CLL/SLL that meets iwCLL diagnostic criteria 3. For I+V cohorts: ECOG performance status of 0-1. For ibrutinib monotherapy cohorts: ECOG performance status of 0-2 4. Active disease meeting at least 1 of the following iwCLL criteria for requiring treatment: a. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. b. Massive (ie, 6 cm below the left costal margin) or progressive or symptomatic splenomegaly. c. Massive nodes (ie, 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy. d. Progressive lymphocytosis with an increase of 50% over a 2-month period, or LDT <6 months. e. Autoimmune complications including anemia or thrombocytopenia poorly responsive to corticosteroids. f. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, spine). g. Disease-

related symptoms as defined by any of the following: i. Unintentional weight loss 10% within the previous 6 months. ii. Significant fatigue (ie, ECOG performance scale 2 or worse; cannot work or unable to perform usual activities). iii. Fevers 100.5°F or 38.0°C for 2 weeks without evidence of infection. iv. Night sweats for 1 month without evidence of infection. 15. Adequate hematologic function independent of transfusion and growth factor support for at least 7 days (except for pegylated G-CSF [pegfilgrastim] and darbepoetin, which require at least 14 days) prior to screening laboratory assessment defined as: a. ANC >750/L independent of growth factor support; b. Platelet count >50,000/L independent of transfusion support for at least 7 days prior to enrollment; c. Hemoglobin >8.0 g/dL independent of transfusion support for >7 days prior to enrollment 16. Adequate hepatic function, defined as: a. Serum AST or ALT 3.0×ULN; b. Bilirubin 1.5×ULN (unless bilirubin rise is due to congenital nonhemolytic hyperbilirubinemias or of non-hepatic origin); c. Prothrombin time/international normal ratio <1.5×ULN and activated partial thromboplastin time <1.5×ULN (unless abnormalities are unrelated to coagulopathy or bleeding disorder) 17. Adequate renal function, defined as follows (using the Cockcroft-Gault equation): a. For I+V cohorts: i. In participants aged <75 years at enrollment, CrCl 45 mL/min; ii. In participants aged 75 years at enrollment, CrCl 60 mL/min. b. For ibrutinib monotherapy cohorts, CrCl 45 mL/min

Criterios de Exclusión

1. Medical history of: a. Other malignancies, except: i. Any malignancy that was not progressing nor requiring treatment change in the last 12 months. ii. Malignancies treated within the last 12 months and considered at very low risk for recurrence: 1. Non-muscle invasive bladder cancer (solitary Ta-PUNLMP or low grade, <3 cm, no CIS). 2. Skin cancer (non-melanoma or melanoma). 3. Non-invasive cervical cancer. 4. Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, localized breast cancer and receiving antihormonal agents. 5. Localized prostate cancer (M0, N0) with a Gleason Score 7a, treated locally only (RP/RT/focal treatment). iii. Other malignancy that is considered at minimal risk of recurrence. b. Uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenia purpura, such as those participants with a declining hemoglobin level or platelet count secondary to autoimmune destruction within the 4 weeks prior to first dose of study treatment, or the need for prednisone >20 mg daily (or corticosteroid equivalent) to treat or control the autoimmune disease. c. Recent infection requiring systemic treatment that is ongoing or was completed 14 days before the first dose of study treatment, or any uncontrolled active systemic infection. d. Known bleeding disorders (eg, von Willebrands disease or hemophilia). e. Stroke or intracranial hemorrhage within 6 months prior to enrollment. f. Difficult to control hypertension (defined as requiring 3 hypertensive medications) or screening systolic blood pressure >160 mmHg or diastolic blood pressure >100 mmHg. For participants whose screening blood pressure exceeds a systolic blood pressure of 160 mmHg or a diastolic blood pressure of 100 mmHg, the investigator should review and manage the participant appropriately according to individual practice. The participant may be rescreened if it can be demonstrated that the blood pressure reading was a single isolated elevation or is subsequently controlled and stable. g. History of myocardial infarction, ventricular arrhythmia, unstable angina, or acute coronary syndrome within 12 months prior to enrollment (if >1 year, cardiology consultation is recommended prior to study enrollment) 2. Known or suspected Richters transformation or CNS involvement 5. Currently active, clinically significant cardiovascular disease, such as uncontrolled arrhythmia or Class II, III, or IV congestive heart failure as defined by the New York Heart Association Functional Classification (see Section 10.8). For participants who in the investigators opinion are considered to have a significant cardiac risk at baseline, the investigator should consider pursuing a cardiology evaluation before screening. It is the investigators responsibility to assess the risks and benefits of subsequent study enrolment 10. Participant received prior systemic anticancer therapy (including but not limited to chemotherapy, targeted therapy, immunomodulating therapy, radiotherapy, and/or monoclonal antibody) for treatment of CLL or SLL 20. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise their wellbeing) or that could prevent, limit, or confound the protocol-specified assessments

Calendario

(Última actualización: 19/01/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/12/2023	17/04/2024	13/05/2024	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

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@imim.es

933160679

Centros

Activo (18/06/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

Activo (20/06/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (17/04/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (17/07/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (20/05/2024)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematology

Activo (10/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Medicamentos

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L01EL01 - IBRUTINIB
Principios Activos: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

JNJ-54179060
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Sin resultados

Multi-cohort Study to Customize Ibrutinib Treatment Regimens for Patients with Previously Untreated Chronic Lymphocytic Leukemia TAILOR

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	122
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-504044-34-00 (CTIS)

Protocol Code
54179060CLL2032

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

Investigated Disease
Untreated Chronic Lymphocytic Leukemia

Scientific Title
Multicohort Study to Customize Ibrutinib Treatment Regimens for Patients with Previously Untreated Chronic Lymphocytic Leukemia

Rationale

Not provided

Main Objective

To evaluate the efficacy of I+V and ibrutinib monotherapy regimens using a tailored treatment approach in which dosing of ibrutinib is either proactively reduced or reactively modified (per the label) in response to AEs, compared with clinical trial-based historical controls of ibrutinib monotherapy and I+V

Primary Endpoints

Best ORR by investigator assessment

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

2. Diagnosis of CLL/SLL that meets iwCLL diagnostic criteria 3. For I+V cohorts: ECOG performance status of 0-1. For ibrutinib monotherapy cohorts: ECOG performance status of 0-2 4. Active disease meeting at least 1 of the following iwCLL criteria for requiring treatment: a. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. b. Massive (ie, 6 cm below the left costal margin) or progressive or symptomatic splenomegaly. c. Massive nodes (ie, 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy. d. Progressive lymphocytosis with an increase of 50% over a 2-month period, or LDT <6 months. e. Autoimmune complications including anemia or thrombocytopenia poorly responsive to corticosteroids. f. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, spine). g. Disease-

related symptoms as defined by any of the following: i. Unintentional weight loss 10% within the previous 6 months. ii. Significant fatigue (ie, ECOG performance scale 2 or worse; cannot work or unable to perform usual activities). iii. Fevers 100.5°F or 38.0°C for 2 weeks without evidence of infection. iv. Night sweats for 1 month without evidence of infection. 15. Adequate hematologic function independent of transfusion and growth factor support for at least 7 days (except for pegylated G-CSF [pegfilgrastim] and darbepoetin, which require at least 14 days) prior to screening laboratory assessment defined as: a. ANC >750/L independent of growth factor support; b. Platelet count >50,000/L independent of transfusion support for at least 7 days prior to enrollment; c. Hemoglobin >8.0 g/dL independent of transfusion support for >7 days prior to enrollment 16. Adequate hepatic function, defined as: a. Serum AST or ALT 3.0×ULN; b. Bilirubin 1.5×ULN (unless bilirubin rise is due to congenital nonhemolytic hyperbilirubinemias or of non-hepatic origin); c. Prothrombin time/international normal ratio <1.5×ULN and activated partial thromboplastin time <1.5×ULN (unless abnormalities are unrelated to coagulopathy or bleeding disorder) 17. Adequate renal function, defined as follows (using the Cockcroft-Gault equation): a. For I+V cohorts: i. In participants aged <75 years at enrollment, CrCl 45 mL/min; ii. In participants aged 75 years at enrollment, CrCl 60 mL/min. b. For ibrutinib monotherapy cohorts, CrCl 45 mL/min

Exclusion criteria

1. Medical history of: a. Other malignancies, except: i. Any malignancy that was not progressing nor requiring treatment change in the last 12 months. ii. Malignancies treated within the last 12 months and considered at very low risk for recurrence: 1. Non-muscle invasive bladder cancer (solitary Ta-PUNLMP or low grade, <3 cm, no CIS). 2. Skin cancer (non-melanoma or melanoma). 3. Non-invasive cervical cancer. 4. Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, localized breast cancer and receiving antihormonal agents. 5. Localized prostate cancer (M0, N0) with a Gleason Score 7a, treated locally only (RP/RT/focal treatment). iii. Other malignancy that is considered at minimal risk of recurrence. b. Uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenia purpura, such as those participants with a declining hemoglobin level or platelet count secondary to autoimmune destruction within the 4 weeks prior to first dose of study treatment, or the need for prednisone >20 mg daily (or corticosteroid equivalent) to treat or control the autoimmune disease. c. Recent infection requiring systemic treatment that is ongoing or was completed 14 days before the first dose of study treatment, or any uncontrolled active systemic infection. d. Known bleeding disorders (eg, von Willebrands disease or hemophilia). e. Stroke or intracranial hemorrhage within 6 months prior to enrollment. f. Difficult to control hypertension (defined as requiring 3 hypertensive medications) or screening systolic blood pressure >160 mmHg or diastolic blood pressure >100 mmHg. For participants whose screening blood pressure exceeds a systolic blood pressure of 160 mmHg or a diastolic blood pressure of 100 mmHg, the investigator should review and manage the participant appropriately according to individual practice. The participant may be rescreened if it can be demonstrated that the blood pressure reading was a single isolated elevation or is subsequently controlled and stable. g. History of myocardial infarction, ventricular arrhythmia, unstable angina, or acute coronary syndrome within 12 months prior to enrollment (if >1 year, cardiology consultation is recommended prior to study enrollment) 2. Known or suspected Richters transformation or CNS involvement 5. Currently active, clinically significant cardiovascular disease, such as uncontrolled arrhythmia or Class II, III, or IV congestive heart failure as defined by the New York Heart Association Functional Classification (see Section 10.8). For participants who in the investigators opinion are considered to have a significant cardiac risk at baseline, the investigator should consider pursuing a cardiology evaluation before screening. It is the investigators responsibility to assess the risks and benefits of subsequent study enrolment 10. Participant received prior systemic anticancer therapy (including but not limited to chemotherapy, targeted therapy, immunomodulating therapy, radiotherapy, and/or monoclonal antibody) for treatment of CLL or SLL 20. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise their wellbeing) or that could prevent, limit, or confound the protocol-specified assessments

Calendar

(Last Update: 19/01/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/12/2023	17/04/2024	13/05/2024	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

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@imim.es

933160679

Sites

Active (18/06/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

Active (20/06/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (17/04/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (17/07/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (20/05/2024)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematology

Active (10/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Medication

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L01EL01 - IBRUTINIB
Active Principles: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

JNJ-54179060
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

No results