A Study to Investigate Progression-Free Survival With Sonrotoclax Plus Obinutuzumab Or Sonrotoclax Plus Rituximab Compared With Venetoclax Plus Rituximab Treatment In Patients With Relapsed and/or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	344
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2024-517131-52-00 (CTIS)

Cod. Protocolo
BGB-11417-303CLL-RR1

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

Enfermedad investigada
Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Título Científico
A Phase 3 Randomized, Open-Label, Multicenter Study of Sonrotoclax Plus Anti-CD20 Antibody Therapies Versus Venetoclax Plus Rituximab in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to compare the efficacy of sonrotoclax plus obinutuzumab versus venetoclax plus rituximab in patients with relapsed and/or refractory (R/R) chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

Variables de Evaluación Primaria

PFS, defined as the time from the date of randomization to the date of disease progression as determined by the blinded independent review committee (BIRC) or death, whichever occurs first.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the efficacy between Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab) as measured by PFS.
To compare the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab) as measured by the uMRD rate at C14D1, complete response/complete response with incomplete hematopoietic recovery (CR/CRi), and overall survival (OS).
To compare the efficacy of Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm B (sonrotoclax plus rituximab).
To evaluate the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy between Arm C (sonrotoclax plus obinutuzumab MRD-guided) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy of combination treatments in all arms in terms of overall response rate (ORR), duration of response (DOR), and time to response (TTR), time to next anti-CLL/SLL treatment (TTNT)
To evaluate the rate of uMRD at various timepoints in all arms
To measure changes in the patient-reported disease- and treatment-specific symptoms and function and to compare the differences between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab), between Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab), between Arm C (sonrotoclax plus obinutuzumab MRD-guided) versus Arm D (venetoclax plus rituximab), between Arm A (sonrotoclax plus obinutuzumab) versus Arm B (sonrotoclax plus rituximab)
To evaluate the safety and tolerability of treatment in all arms

Variables de Evaluación Secundaria

PFS, defined as the time from the date of randomization to the date of disease progression as determined by the

BIRC or death, whichever occurs first. Undetectable minimal residual disease at < 10-4 sensitivity (uMRD4) rate in peripheral blood at C14D1 Visit based on next-generation sequencing (NGS [clonoSEQ]). Complete response rate (CRR), defined as the proportion of patients that achieve a best response of CR or CRi (CR/CRi), as determined by the BIRC. OS, defined as the time from the date of randomization to the date of death. PFS per investigator assessment. CRR per the BIRC and investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and Posttreatment follow-up [PTFU]1) based on NGS (clonoSEQ). PFS per BIRC and investigator assessment. CRR per BIRC and investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and PTFU1) based on NGS (clonoSEQ). Rate of uMRD4 (C8D1, C11D1 and PTFU1) based on NGS (clonoSEQ). CRR per investigator assessment. PFS per investigator assessment. PFS per investigator assessment. CRR per investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and PTFU1) based on NGS (clonoSEQ). ORR, defined as the proportion of patients that achieve a best response of partial response (PR) or better, as determined by the BIRC and investigator assessment. DOR, defined as the time from the date that response criteria were first met to the date of first documentation of disease progression or death, whichever occurred first per the BIRC and investigator assessment. TTR, defined as the time from the date of randomization to the date response criteria were first met, per the BIRC and investigator assessment. TTNT, defined as the time from the date of randomization to the date of next anti-CLL/SLL treatment. (The BIRC assessments are applicable for Arms A, B, and D only.) Rate of uMRD4 in peripheral blood at C8D1, C11D1, C14D1, C20D1, PTFU1, and subsequent follow-up timepoints Global health status/QoL and physical functioning as measured by EORTC-QLQ-C30 and Symptom burden due to disease or treatment (symptom burden) and physical condition/fatigue (fatigue) as measured by EORTC QLQ-CLL17. Safety (adverse events, serious adverse events, changes from baseline in clinical laboratory tests, physical examinations, and vital signs).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients aged 18 years with a confirmed diagnosis of CLL/SLL, per the iwCLL 2018 criteria (Hallek et al 2018). Patients must have 1 prior therapy for CLL/SLL. For each line of therapy, patients must receive at least 2 cycles of this therapy. For patients who received a BCL2i, only those with CLL/SLL who received BCL2i in the first line setting with fixed duration therapy, have a remission for 3 years, and have a time interval of 2 years from the last dose of BCL2i to screening, are eligible. Patients should be informed about their options to choose other approved CLL/SLL therapies in this setting. Indications for CLL/SLL therapy are met by one of the criteria per the iwCLL 2018 criteria, with minor modification as discussed in the main protocol. Eastern Cooperative Oncology Group (ECOG) Performance status 0, 1, or 2. Adequate marrow function as defined by: Absolute neutrophil count 1.0 x 109 cells/L with an exception for patients with bone marrow involvement, in which case the absolute neutrophil count must be 0.75 x 109 cells/L (without growth factor support within the past 7 days). Platelet counts 75 x 109 cells/L; in cases of thrombocytopenia clearly due to marrow involvement of CLL (per the discretion of the investigator), the platelet count should be 30 x 109 cells/L (without growth factor support or transfusion within the past 7 days). Hemoglobin > 75 g/L (may be posttransfusion). Adequate liver function as indicated by aspartate aminotransferase and alanine aminotransferase 2.5 x upper limits of normal (ULNs) value; serum total bilirubin 1.5 x ULNs (unless documented Gilbert syndrome where total bilirubin 3 x ULNs). Adequate renal function, defined by a value 30 mL/min, determined either by creatinine clearance directly measured with a 24-hour urine collection or via estimated glomerular filtration rate calculated according to the Chronic Kidney Disease Epidemiology Collaboration equation. Life expectancy > 6 months.

Criterios de Exclusión

No active infection including hepatitis B or C virus or HIV at the time of study treatment initiation.
No active prolymphocytic leukemia or currently suspected Richters transformation at the time of consideration for study.
No ongoing clinically significant cardiovascular or pulmonary disease that prevents participation.
No central nervous system involvement by CLL/SLL.
No history of prior or active malignancy within 18 months, except for conditions as listed below and as long as patients have recovered from the acute side effects incurred because of previous therapy: Adequately treated nonmelanoma skin cancer or lentigo maligna without evidence of disease. Adequately treated cervical carcinoma in situ without evidence of disease. Localized prostate cancer with Gleason score 6 or controlled prostate cancer with androgen deprivation treatment. Treated early-stage breast cancer with or without hormonal therapy.
No other active antineoplastic treatment.
No CYP3A4 moderate or strong inhibitors or CYP3A4 moderate or strong inducers.

Calendario

(Última actualización: 05/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
29/09/2025	17/12/2025	17/12/2025	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

BeOne Medicines AG Switzerland

Aeschengraben 27

Contact Person

BeOne Medical Officer

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario de La Princesa

C/ Diego de León, 62 28006 Madrid

ceim.hlpr@salud.madrid.org

Centros

Activo (20/11/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (19/11/2025)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Activo (04/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (25/11/2025)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Activo (07/11/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (05/12/2025)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (14/11/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (19/11/2025)

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Hematology

Activo (18/02/2026)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01FA03 - L01FA03- OBINUTUZUMAB
Principios Activos: N/A

Huérfano Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

MabThera 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

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

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

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

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

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

Experimental

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

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

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Sin resultados

A Study to Investigate Progression-Free Survival With Sonrotoclax Plus Obinutuzumab Or Sonrotoclax Plus Rituximab Compared With Venetoclax Plus Rituximab Treatment In Patients With Relapsed and/or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	344
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2024-517131-52-00 (CTIS)

Protocol Code
BGB-11417-303CLL-RR1

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

Investigated Disease
Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Scientific Title
A Phase 3 Randomized, Open-Label, Multicenter Study of Sonrotoclax Plus Anti-CD20 Antibody Therapies Versus Venetoclax Plus Rituximab in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Rationale

Not provided

Main Objective

The primary objective of this study is to compare the efficacy of sonrotoclax plus obinutuzumab versus venetoclax plus rituximab in patients with relapsed and/or refractory (R/R) chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

Primary Endpoints

PFS, defined as the time from the date of randomization to the date of disease progression as determined by the blinded independent review committee (BIRC) or death, whichever occurs first.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the efficacy between Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab) as measured by PFS.
To compare the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab) as measured by the uMRD rate at C14D1, complete response/complete response with incomplete hematopoietic recovery (CR/CRi), and overall survival (OS).
To compare the efficacy of Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm B (sonrotoclax plus rituximab).
To evaluate the efficacy between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy between Arm C (sonrotoclax plus obinutuzumab MRD-guided) versus Arm D (venetoclax plus rituximab).
To evaluate the efficacy of combination treatments in all arms in terms of overall response rate (ORR), duration of response (DOR), and time to response (TTR), time to next anti-CLL/SLL treatment (TTNT)
To evaluate the rate of uMRD at various timepoints in all arms
To measure changes in the patient-reported disease- and treatment-specific symptoms and function and to compare the differences between Arm A (sonrotoclax plus obinutuzumab) versus Arm D (venetoclax plus rituximab), between Arm B (sonrotoclax plus rituximab) versus Arm D (venetoclax plus rituximab), between Arm C (sonrotoclax plus obinutuzumab MRD-guided) versus Arm D (venetoclax plus rituximab), between Arm A (sonrotoclax plus obinutuzumab) versus Arm B (sonrotoclax plus rituximab)
To evaluate the safety and tolerability of treatment in all arms

Secondary Endpoints

PFS, defined as the time from the date of randomization to the date of disease progression as determined by the

BIRC or death, whichever occurs first. Undetectable minimal residual disease at < 10-4 sensitivity (uMRD4) rate in peripheral blood at C14D1 Visit based on next-generation sequencing (NGS [clonoSEQ]). Complete response rate (CRR), defined as the proportion of patients that achieve a best response of CR or CRi (CR/CRi), as determined by the BIRC. OS, defined as the time from the date of randomization to the date of death. PFS per investigator assessment. CRR per the BIRC and investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and Posttreatment follow-up [PTFU]1) based on NGS (clonoSEQ). PFS per BIRC and investigator assessment. CRR per BIRC and investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and PTFU1) based on NGS (clonoSEQ). Rate of uMRD4 (C8D1, C11D1 and PTFU1) based on NGS (clonoSEQ). CRR per investigator assessment. PFS per investigator assessment. PFS per investigator assessment. CRR per investigator assessment. OS. Rate of uMRD4 (C8D1, C11D1, C14D1, and PTFU1) based on NGS (clonoSEQ). ORR, defined as the proportion of patients that achieve a best response of partial response (PR) or better, as determined by the BIRC and investigator assessment. DOR, defined as the time from the date that response criteria were first met to the date of first documentation of disease progression or death, whichever occurred first per the BIRC and investigator assessment. TTR, defined as the time from the date of randomization to the date response criteria were first met, per the BIRC and investigator assessment. TTNT, defined as the time from the date of randomization to the date of next anti-CLL/SLL treatment. (The BIRC assessments are applicable for Arms A, B, and D only.) Rate of uMRD4 in peripheral blood at C8D1, C11D1, C14D1, C20D1, PTFU1, and subsequent follow-up timepoints Global health status/QoL and physical functioning as measured by EORTC-QLQ-C30 and Symptom burden due to disease or treatment (symptom burden) and physical condition/fatigue (fatigue) as measured by EORTC QLQ-CLL17. Safety (adverse events, serious adverse events, changes from baseline in clinical laboratory tests, physical examinations, and vital signs).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients aged 18 years with a confirmed diagnosis of CLL/SLL, per the iwCLL 2018 criteria (Hallek et al 2018). Patients must have 1 prior therapy for CLL/SLL. For each line of therapy, patients must receive at least 2 cycles of this therapy. For patients who received a BCL2i, only those with CLL/SLL who received BCL2i in the first line setting with fixed duration therapy, have a remission for 3 years, and have a time interval of 2 years from the last dose of BCL2i to screening, are eligible. Patients should be informed about their options to choose other approved CLL/SLL therapies in this setting. Indications for CLL/SLL therapy are met by one of the criteria per the iwCLL 2018 criteria, with minor modification as discussed in the main protocol. Eastern Cooperative Oncology Group (ECOG) Performance status 0, 1, or 2. Adequate marrow function as defined by: Absolute neutrophil count 1.0 x 109 cells/L with an exception for patients with bone marrow involvement, in which case the absolute neutrophil count must be 0.75 x 109 cells/L (without growth factor support within the past 7 days). Platelet counts 75 x 109 cells/L; in cases of thrombocytopenia clearly due to marrow involvement of CLL (per the discretion of the investigator), the platelet count should be 30 x 109 cells/L (without growth factor support or transfusion within the past 7 days). Hemoglobin > 75 g/L (may be posttransfusion). Adequate liver function as indicated by aspartate aminotransferase and alanine aminotransferase 2.5 x upper limits of normal (ULNs) value; serum total bilirubin 1.5 x ULNs (unless documented Gilbert syndrome where total bilirubin 3 x ULNs). Adequate renal function, defined by a value 30 mL/min, determined either by creatinine clearance directly measured with a 24-hour urine collection or via estimated glomerular filtration rate calculated according to the Chronic Kidney Disease Epidemiology Collaboration equation. Life expectancy > 6 months.

Exclusion criteria

No active infection including hepatitis B or C virus or HIV at the time of study treatment initiation.
No active prolymphocytic leukemia or currently suspected Richters transformation at the time of consideration for study.
No ongoing clinically significant cardiovascular or pulmonary disease that prevents participation.
No central nervous system involvement by CLL/SLL.
No history of prior or active malignancy within 18 months, except for conditions as listed below and as long as patients have recovered from the acute side effects incurred because of previous therapy: Adequately treated nonmelanoma skin cancer or lentigo maligna without evidence of disease. Adequately treated cervical carcinoma in situ without evidence of disease. Localized prostate cancer with Gleason score 6 or controlled prostate cancer with androgen deprivation treatment. Treated early-stage breast cancer with or without hormonal therapy.
No other active antineoplastic treatment.
No CYP3A4 moderate or strong inhibitors or CYP3A4 moderate or strong inducers.

Calendar

(Last Update: 05/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
29/09/2025	17/12/2025	17/12/2025	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

BeOne Medicines AG Switzerland

Aeschengraben 27

Contact Person

BeOne Medical Officer

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario de La Princesa

C/ Diego de León, 62 28006 Madrid

ceim.hlpr@salud.madrid.org

Sites

Active (20/11/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (19/11/2025)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Active (04/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (25/11/2025)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Active (07/11/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (05/12/2025)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Active (14/11/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (19/11/2025)

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Hematology

Active (18/02/2026)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L01FA03 - L01FA03- OBINUTUZUMAB
Active Principles: N/A

Orphan Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

MabThera 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A

Experimental

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

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

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

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

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

Experimental

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

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

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

No results