A Phase 2/3 study to evaluate safety and efficacy of the combination of Bel- CHOP/ Fol-COP drugs against CHOP in newly diagnosed Peripheral T-Cell Lymphoma (blood cancer) patients

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II , Fase III	354
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis, farmacogenética	NO

Información

Identificador
2023-507803-76-00 (CTIS)

Cod. Protocolo
SPI-BEL-301

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

Enfermedad investigada
Peripheral T-Cell Lymphoma

Título Científico
A Phase 2/3, Randomized, Open-Label Study Comparing the Efficacy and Safety of the Combination of Beleodaq-CHOP or Folotyn-COP to the CHOP Regimen Alone in Newly Diagnosed Patients with Peripheral T- Cell Lymphoma

Justificación

No aportado

Objetivo Principal

Part 1 (Dose Finding); Select which of the two dose levels for Belinostat and Pralatrexate associated with CHOP is best suitable for the Part 2 study based on safety and ORR at 3 months.
Part 2 (Efficacy and Safety): To compare the PFS of patients with newly diagnosed PTCL treated for up to 6 cycles with Beleodaq (belinostat) in combination with CHOP (Bel-CHOP) or Folotyn (pralatrexate injection) in combination with COP (Fol-COP) to CHOP alone

Variables de Evaluación Primaria

The primary endpoint is PFS, defined as the time (months) from randomization to the first documented PD or death, whichever occurs first.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the OS for patients with newly diagnosed PTCL treated with Bel-CHOP or Fol-COP to CHOP alone To compare the ORR for patients with newly diagnosed PTCL treated with Bel-CHOP or Fol-COP to CHOP alone Treatment compliance

Variables de Evaluación Secundaria

Overall survival is defined as time from randomization to death due to any cause. Overall survival will be censored at the date patients were last known to be alive. Objective response rate is defined as the percentage of patients who have a CR or PR as their best objective response. Treatment compliance- Dose delays and reduction of the treatment arms will be evaluated.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Patient with newly diagnosed, untreated histology-proven PTCL based on local pathology review who is eligible for receiving Belinostat, Pralatrexate, and CHOP. Pathology material must be available at the site for each patient before enrollment so that it can be sent to the Sponsor (or designee) for later confirmation. The following subtypes, as defined by the updated WHO classification, may be included. This information should be available for eligibility: a. Pathology subtype: o Peripheral T-cell lymphoma, not otherwise specified o Angioimmunoblastic T-cell lymphoma o Anaplastic lymphoma kinase (ALK)-negative anaplastic large-cell lymphoma (ALCL) patients are eligible only if Brentuximab Vedotin (BV) is not commercially approved for use, not available in the country or patient is contraindicated to receive BV. o Follicular T-cell lymphoma o Others: Extra-nodal natural killer/T-cell lymphoma, nasal type; enteropathy-associated T-cell lymphoma; hepatosplenic T-cell lymphoma; and subcutaneous panniculitis-like T-cell lymphoma b. CD30 expression and T-cell Follicular Helper (TFH) phenotype status must be available for documentation. 2. Patient has at least 1 site of measurable disease according to Response Evaluation Criteria in Lymphoma (RECIL) 2017 criteria as assessed by local Investigator (Appendix 3) 3. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 2 4. For Part 1 (Dose Finding) - Patient has adequate hematological, hepatic, and renal function as defined by: a. Absolute neutrophil count 1.5 × 10/L or 1.0 × 10/L if evidence of bone marrow involvement b. Platelet count 100×10/L or 75×10/L if evidence of bone marrow involvement c. Total bilirubin 1.5 mg/dL d. Aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT), alanine aminotransferase (ALT)/serum glutamic-pyruvic transaminase (SGPT) 3×upper limit of normal (ULN; AST/ALT 5×ULN if documented hepatic involvement with lymphoma) e. Calculated creatinine clearance of 60 mL/min 5. Part 2 (Efficacy and Safety)- disease related hypoplasia, hepatological or renal dysfunction can be included if any of the treatment groups can be administered based on package insert recommendation with the following restrictions: a. Absolute neutrophil count 1.5 × 10/L or 1.0 × 10/L if evidence of bone marrow involvement b. Platelet count 100×10/L or 75×10/L if evidence of bone marrow involvement c. Total bilirubin 1.5 mg/dL d. Aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT), alanine aminotransferase (ALT)/serum glutamic-pyruvic transaminase (SGPT) 3 x the upper limit of normal (ULN; AST/ALT 5×ULN if documented hepatic involvement with lymphoma) e. Calculated creatinine clearance of 60 mL/min 6. UGT1A1 genotype has been characterized (see Belinostat dose modifications if abnormal) and must be available for documentation. 7. Patient must be willing and capable of giving written informed consent and must be able to adhere to dosing and visit schedules and meet all study requirements 8. Patient (male or female) is at least 18 years of age at the time of informed consent 9. Patient is willing to practice 2 forms of contraception, one of which must be a barrier method, from study entry until at least 6 months after the last dose of study treatment (Please refer to Appendix 4 for contraception guidance). 10. Females of childbearing potential must have a negative urine pregnancy test within 4 weeks prior to the first day of study treatment. Females who are postmenopausal for at least 1 year (defined as more than 12 months since last menses) or are surgically sterilized do not require this test. Please refer to Appendix 4 for further details.

Criterios de Exclusión

1. Patients with a diagnosis of: a. Precursor T-cell lymphoma or leukemia b. Adult T-cell lymphoma/leukemia c. T-cell prolymphocytic leukemia d. T-cell large granular lymphocytic leukemia e. Primary cutaneous type ALCL f. Cutaneous T-cell lymphoma (mycosis fungoides/Sezary syndrome) g. ALCL if they can be treated with Brentuximab Vedotin (BV) 2) Patients taking drugs which are potent UGT1A1 inhibitors must discontinue one week before dosing before randomization; drug can be resumed if the treatment doesnt include belinostat 3) Patient with an active concurrent malignancy/life-threatening disease with the exception of non-melanoma skin tumors and in situ cervical cancer if they have received treatment resulting in complete resolution of the cancer and currently have no clinical, radiologic, or laboratory evidence of active or recurrent disease. If there is a history of prior malignancies/life-threatening diseases, the patient must be disease free for at least 5 years 4) Prior HDAC inhibitor or pralatrexate therapy 5) Any known cardiac abnormalities such as baseline prolongation of QT/corrected QT (QTc) interval (ie, demonstration of a QTc interval >450 msec); long QT syndrome; myocardial infarction within 6 months prior to starting study; history of significant cardiovascular disease; the required use of a concomitant medication that may cause Torsades de Pointes 6) Patient with uncontrolled hypertension 7) Patients status on the following: a) Has a known HIV-positive diagnosis with uncontrolled and detectable viral load b) Has Hepatitis B or Hepatitis C virus diagnosis with uncontrolled and detectable viral load or immunological evidence of chronic active disease 8) Patient with central nervous system metastasis 9) Patient with an active uncontrolled infection, underlying medical condition, laboratory abnormality, or other serious illness that would impair the ability of the patient to receive protocol treatment 10)

Patient who has used any investigational drugs, biologics, or devices within 28 days prior to study treatment or plans to use any of these during the course of the study 11) Patient with a known history of drug or alcohol abuse 12) Pregnant or breastfeeding women

Calendario

(Última actualización: 07/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/07/2024	05/11/2024	11/12/2024	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

Acrotech Biopharma Inc. United States

279 Princeton Hightstown Road

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (09/12/2024)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (05/12/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (05/11/2024)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Activo (12/03/2025)

Hospital Universitario Basurto

Bilbao

VIZCAYA/BIZKAIA

Hematology

Activo (21/01/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Activo (19/12/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (07/02/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (05/11/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (19/11/2024)

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Activo (20/06/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

PREDNISONE
TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

DOXORUBICIN
SOLUTION FOR INJECTION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

Pralatrexate
SOLUTION FOR INJECTION
INTRAVENOUS USE

-
Principios Activos: N/A
Huérfano
Experimental

Belinostat
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A
Huérfano
Experimental

Sin resultados

A Phase 2/3 study to evaluate safety and efficacy of the combination of Bel- CHOP/ Fol-COP drugs against CHOP in newly diagnosed Peripheral T-Cell Lymphoma (blood cancer) patients

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II , Phase III	354
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose, pharmacogenetics	NO

Information

Identifier
2023-507803-76-00 (CTIS)

Protocol Code
SPI-BEL-301

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

Investigated Disease
Peripheral T-Cell Lymphoma

Scientific Title
A Phase 2/3, Randomized, Open-Label Study Comparing the Efficacy and Safety of the Combination of Beleodaq-CHOP or Folotyn-COP to the CHOP Regimen Alone in Newly Diagnosed Patients with Peripheral T- Cell Lymphoma

Rationale

Not provided

Main Objective

Part 1 (Dose Finding); Select which of the two dose levels for Belinostat and Pralatrexate associated with CHOP is best suitable for the Part 2 study based on safety and ORR at 3 months.
Part 2 (Efficacy and Safety): To compare the PFS of patients with newly diagnosed PTCL treated for up to 6 cycles with Beleodaq (belinostat) in combination with CHOP (Bel-CHOP) or Folotyn (pralatrexate injection) in combination with COP (Fol-COP) to CHOP alone

Primary Endpoints

The primary endpoint is PFS, defined as the time (months) from randomization to the first documented PD or death, whichever occurs first.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the OS for patients with newly diagnosed PTCL treated with Bel-CHOP or Fol-COP to CHOP alone To compare the ORR for patients with newly diagnosed PTCL treated with Bel-CHOP or Fol-COP to CHOP alone Treatment compliance

Secondary Endpoints

Overall survival is defined as time from randomization to death due to any cause. Overall survival will be censored at the date patients were last known to be alive. Objective response rate is defined as the percentage of patients who have a CR or PR as their best objective response. Treatment compliance- Dose delays and reduction of the treatment arms will be evaluated.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Patient with newly diagnosed, untreated histology-proven PTCL based on local pathology review who is eligible for receiving Belinostat, Pralatrexate, and CHOP. Pathology material must be available at the site for each patient before enrollment so that it can be sent to the Sponsor (or designee) for later confirmation. The following subtypes, as defined by the updated WHO classification, may be included. This information should be available for eligibility: a. Pathology subtype: o Peripheral T-cell lymphoma, not otherwise specified o Angioimmunoblastic T-cell lymphoma o Anaplastic lymphoma kinase (ALK)-negative anaplastic large-cell lymphoma (ALCL) patients are eligible only if Brentuximab Vedotin (BV) is not commercially approved for use, not available in the country or patient is contraindicated to receive BV. o Follicular T-cell lymphoma o Others: Extra-nodal natural killer/T-cell lymphoma, nasal type; enteropathy-associated T-cell lymphoma; hepatosplenic T-cell lymphoma; and subcutaneous panniculitis-like T-cell lymphoma b. CD30 expression and T-cell Follicular Helper (TFH) phenotype status must be available for documentation. 2. Patient has at least 1 site of measurable disease according to Response Evaluation Criteria in Lymphoma (RECIL) 2017 criteria as assessed by local Investigator (Appendix 3) 3. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 2 4. For Part 1 (Dose Finding) - Patient has adequate hematological, hepatic, and renal function as defined by: a. Absolute neutrophil count 1.5 × 10/L or 1.0 × 10/L if evidence of bone marrow involvement b. Platelet count 100×10/L or 75×10/L if evidence of bone marrow involvement c. Total bilirubin 1.5 mg/dL d. Aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT), alanine aminotransferase (ALT)/serum glutamic-pyruvic transaminase (SGPT) 3×upper limit of normal (ULN; AST/ALT 5×ULN if documented hepatic involvement with lymphoma) e. Calculated creatinine clearance of 60 mL/min 5. Part 2 (Efficacy and Safety)- disease related hypoplasia, hepatological or renal dysfunction can be included if any of the treatment groups can be administered based on package insert recommendation with the following restrictions: a. Absolute neutrophil count 1.5 × 10/L or 1.0 × 10/L if evidence of bone marrow involvement b. Platelet count 100×10/L or 75×10/L if evidence of bone marrow involvement c. Total bilirubin 1.5 mg/dL d. Aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT), alanine aminotransferase (ALT)/serum glutamic-pyruvic transaminase (SGPT) 3 x the upper limit of normal (ULN; AST/ALT 5×ULN if documented hepatic involvement with lymphoma) e. Calculated creatinine clearance of 60 mL/min 6. UGT1A1 genotype has been characterized (see Belinostat dose modifications if abnormal) and must be available for documentation. 7. Patient must be willing and capable of giving written informed consent and must be able to adhere to dosing and visit schedules and meet all study requirements 8. Patient (male or female) is at least 18 years of age at the time of informed consent 9. Patient is willing to practice 2 forms of contraception, one of which must be a barrier method, from study entry until at least 6 months after the last dose of study treatment (Please refer to Appendix 4 for contraception guidance). 10. Females of childbearing potential must have a negative urine pregnancy test within 4 weeks prior to the first day of study treatment. Females who are postmenopausal for at least 1 year (defined as more than 12 months since last menses) or are surgically sterilized do not require this test. Please refer to Appendix 4 for further details.

Exclusion criteria

1. Patients with a diagnosis of: a. Precursor T-cell lymphoma or leukemia b. Adult T-cell lymphoma/leukemia c. T-cell prolymphocytic leukemia d. T-cell large granular lymphocytic leukemia e. Primary cutaneous type ALCL f. Cutaneous T-cell lymphoma (mycosis fungoides/Sezary syndrome) g. ALCL if they can be treated with Brentuximab Vedotin (BV) 2) Patients taking drugs which are potent UGT1A1 inhibitors must discontinue one week before dosing before randomization; drug can be resumed if the treatment doesnt include belinostat 3) Patient with an active concurrent malignancy/life-threatening disease with the exception of non-melanoma skin tumors and in situ cervical cancer if they have received treatment resulting in complete resolution of the cancer and currently have no clinical, radiologic, or laboratory evidence of active or recurrent disease. If there is a history of prior malignancies/life-threatening diseases, the patient must be disease free for at least 5 years 4) Prior HDAC inhibitor or pralatrexate therapy 5) Any known cardiac abnormalities such as baseline prolongation of QT/corrected QT (QTc) interval (ie, demonstration of a QTc interval >450 msec); long QT syndrome; myocardial infarction within 6 months prior to starting study; history of significant cardiovascular disease; the required use of a concomitant medication that may cause Torsades de Pointes 6) Patient with uncontrolled hypertension 7) Patients status on the following: a) Has a known HIV-positive diagnosis with uncontrolled and detectable viral load b) Has Hepatitis B or Hepatitis C virus diagnosis with uncontrolled and detectable viral load or immunological evidence of chronic active disease 8) Patient with central nervous system metastasis 9) Patient with an active uncontrolled infection, underlying medical condition, laboratory abnormality, or other serious illness that would impair the ability of the patient to receive protocol treatment 10)

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Calendar

(Last Update: 07/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/07/2024	05/11/2024	11/12/2024	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

Acrotech Biopharma Inc. United States

279 Princeton Hightstown Road

Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (09/12/2024)

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Madrid

MADRID

Hematology

Active (05/12/2024)

Clinica Universidad De Navarra

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Barcelona

BARCELONA

Hematology

Active (12/03/2025)

Hospital Universitario Basurto

Bilbao

VIZCAYA/BIZKAIA

Hematology

Active (21/01/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Active (19/12/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (07/02/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (05/11/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (19/11/2024)

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Active (20/06/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

PREDNISONE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

DOXORUBICIN
SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

Pralatrexate
SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Active Principles: N/A

Orphan

Experimental

Belinostat
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Orphan

Experimental

No results