

A study to evaluate acalabrutinib, in combination with the R-CHOP standard of care, for previously untreated mantle cell lymphoma in Spain.

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase II

Participantes esperados

55

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia

Terapia avanzada

NO

Información

Identificador

2025-521152-34-00 (CTIS)

Cod. Protocolo

D8220L00087

Área terapéutica

Enfermedades [C] - Hematología [C15]

Enfermedad investigada

mantle cell lymphoma (MCL)

Título Científico

The SOUND-MCL study: A single-arm, open-label, multicenter, phase II study of acalabrutinib, in combination with the R-CHOP standard of care, for previously untreated mantle cell lymphoma in Spain

Justificación

No aportado

Objetivo Principal

To assess the efficacy in terms of treatment response to acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

Variables de Evaluación Primaria

Investigator-assessed best ORR (CR+PR) as per the Lugano Classification for NHL. Timeframe: 1 year

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To further assess the efficacy of acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

To assess the safety and tolerability profile of acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

Variables de Evaluación Secundaria

TTR, defined as the time from the date of acalabrutinib start to the first investigator-assessed CR or PR per the Lugano Classification for NHL. Measure of interest: median TTR.

DoR, defined as the time from the first documentation of investigator-assessed CR or PR to disease progression per the Lugano Classification for NHL or death from any cause in the absence of disease progression. Measure of interest: 30-month DoR

PFS, defined as the time from the date of acalabrutinib start to investigator-assessed disease progression as per the Lugano Classification for NHL or death from any cause, whichever occurs first. Measure of interest: 30-month PFS.

OS, defined as the time from the date of acalabrutinib start to the date of death from any cause. Measure of interest: 30-month OS

Describe the number and percentage of patients with each MedDRA coded and CTCAE graded adverse (AEs) and serious adverse events (SAEs).

Incidence of AEs of clinical interest for acalabrutinib.

Incidence of grade 3 AEs.

Incidence of AEs leading to acalabrutinib dose modification, temporary interruption or permanent discontinuation.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Adult (aged 18 years) men or women.

Willing and able to participate in all required evaluations and procedures in this study protocol including swallowing tablets without difficulty

Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information (in accordance with national and local patient privacy regulations).

Unsuitable for autologous stem cell transplantation

WOCBP who are sexually active must use highly effective methods of contraception during the study treatment and for 12 months after the last dose of rituximab or cyclophosphamide, 6 months after the last dose of doxorubicin, 30 days after the last dose of vincristine, and 2 days after the last dose of acalabrutinib, whichever is the longest. NOTE: Female participants should be stable on the chosen method of contraception for a minimum of 3 months before entering a trial.

Male patients should use barrier contraception (ie, condoms) from the time of screening until 12 months after the last dose of rituximab or cyclophosphamide, 6 months after the last dose of doxorubicin, 30 days after the last dose of vincristine, and 2 days after the last dose of acalabrutinib, whichever is longest. Male patients wishing to father children in the future should be advised to arrange for the freezing of sperm prior to the start of study treatment. NOTE: Female partners should be advised to use accepted contraception during their partners study treatment and for 12 months after the last dose of rituximab or cyclophosphamide, 6 months after the last dose of doxorubicin, 30 days after the last dose of vincristine, and 2 days after the last dose of acalabrutinib, whichever is longest.

Pathologically confirmed MCL, with documentation of chromosome translocation t(11;14)(q13;q32) and/or overexpression of cyclin D1 in association with other relevant markers

MCL requiring treatment and for which no prior systemic anticancer therapies have been received

Presence of radiologically measurable lymphadenopathy, splenomegaly and/or extranodal lymphoid malignancy

Eastern Cooperative Oncology Group (ECOG) performance status of 2.

Men who are sexually active and can beget children must agree to use highly effective forms of contraception during the study treatment and for 12 months after the last dose of rituximab or cyclophosphamide, 6 months after the last dose of doxorubicin, 30 days after the last dose of vincristine, and 2 days after the last dose of acalabrutinib, whichever is longest.

Men must agree to refrain from sperm donation during the study treatment and for 12 months after the last dose of rituximab or cyclophosphamide, 6 months after the last dose of doxorubicin, 30 days after the last dose of vincristine, and 2 days after the last dose of acalabrutinib, whichever is longest

Criterios de Exclusión

History of prior malignancy except for the following: a. Malignancy treated with curative intent and with no evidence of active disease present for more than 2 years before screening and felt to be at low risk for recurrence by treating physician. Note: Provided they meet other eligibility criteria, subjects who are receiving hormonal therapy alone are allowed to enroll on study. b. Adequately treated lentigo maligna melanoma without current evidence of disease or adequately controlled nonmelanomatous skin cancer. c. Adequately treated carcinoma in situ without current evidence of disease. History of stroke or intracranial hemorrhage within 6 months of first dose of study drug. History of bleeding diathesis (e.g., hemophilia or von Willebrand disease). Subjects for whom the goal of therapy is tumor debulking before stem cell transplant Presence of a gastrointestinal ulcer diagnosed by endoscopy within 3 months before first dose of study drug. Requires or receiving anticoagulation with warfarin or equivalent vitamin K antagonists (e.g., phenprocoumon) within 7 days of first dose of study drug. Requires treatment with a strong CYP3A inhibitor/inducer Concurrent participation in another therapeutic clinical trial. Active cytomegalovirus (CMV) infection (active viremia as evidenced by positive PCR result for CMV DNA). History of confirmed progressive multifocal leukoencephalopathy (PML). Any history of central nervous system (CNS) lymphoma or leptomeningeal disease Prothrombin time/international normalized ratio (INR) or activated partial thromboplastin time (aPTT) (in the absence

of a lupus anticoagulant) $>2.0 \times \text{ULN}$. Exception: Subjects receiving a vitamin K antagonist are excluded; however, those receiving other anticoagulant therapy who have a higher INR/aPTT may be permitted to enroll to this study after discussion with the medical monitor. Uncontrolled autoimmune hemolytic anemia (AIHA) or idiopathic thrombocytopenic purpura (ITP). Major surgical procedure within 28 days before first dose of study drug. Note: If a subject had major surgery, they must have recovered adequately from any toxicity and/or complications from the intervention before the first dose of study drug. Significant cardiovascular disease such as uncontrolled or untreated symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of first dose of study drug, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification at screening. Exception: Subjects with controlled, asymptomatic atrial fibrillation during screening are allowed to enroll on study. Absolute neutrophil count (ANC) $<1.0 \times 10^9/\text{L}$ or platelet count $<75 \times 10^9/\text{L}$; for subjects with disease involvement in the bone marrow, ANC $<0.75 \times 10^9/\text{L}$ or platelet count $<50 \times 10^9/\text{L}$. Subjects will only be considered eligible if peripheral blood counts can be maintained independent of growth factors or transfusions during the screening period. Total bilirubin $>1.5 \times$ upper limit normal (ULN) unless other reason known (e.g. Gilbert Syndrome, or due to lymphoma involvement); or aspartate aminotransferase (AST) or alanine transaminase (ALT) $>2.5 \times \text{ULN}$. Estimated creatinine clearance of $<30 \text{ mL/min}$, calculated using the formula of Cockcroft and Gault $[(140 - \text{age}) \text{ mass (kg)} / (72 \text{ creatinine mg/dL}) \text{ multiply by } 0.85 \text{ if female}]$. Subjects who are deemed by the treating physician to be unfit to tolerate the R-CHOP regimen. Pregnant or breastfeeding women. Malabsorption syndrome, disease significantly affecting gastrointestinal function, resection of the stomach, extensive small bowel resection that is likely to affect absorption, symptomatic inflammatory bowel disease, partial or complete bowel obstruction, or gastric restrictions and bariatric surgery, such as gastric bypass. Uncontrolled active systemic fungal, bacterial, viral, or other infection (defined as exhibiting ongoing signs/symptoms related to the infection and without improvement, despite appropriate antibiotics or other treatment), or intravenous anti-infective treatment within 2 weeks before first dose of study drug. Known history of infection with human immunodeficiency virus (HIV). Ongoing immunosuppressive therapy, including systemic (e.g., IV or oral) corticosteroids within 2 weeks before the first dose of study drug. Note: Subjects may use topical or inhaled corticosteroids or low-dose steroids (20 mg prednisone equivalent/day for 2 weeks) as a therapy for comorbid conditions and/or pre-phase treatment up to 100 mg/day or equivalent (for a maximum of 10 days prior to beginning study treatment) in participants with bulky disease, systemic symptoms, compressive disease, impaired liver function or cytopenias due to lymphoma, or rapidly progressing adenopathies. During study participation, subjects will receive corticosteroids as part of the R-CHOP regimen according to institution standards. Subjects may also receive systemic (e.g., IV or oral) corticosteroids as needed for treatment-emergent comorbid conditions. Known history of anaphylaxis or hypersensitivity to any study drug, or any of their components. Serologic status reflecting active hepatitis B or C infection. a. Subjects who are anti-HBc positive and who are surface antigen negative will need to have a negative polymerase chain reaction (PCR) result before the first dose of study drug. Those who are HbsAg positive or hepatitis B PCR positive will be excluded. b. Subjects who are hepatitis C antibody positive will need to have a negative PCR result before the first dose of study drug. Those who are hepatitis C PCR positive will be excluded. Received a live virus vaccination within 28 days of first dose of study drug.

Calendario

(Última actualización: 19/06/2026)

Autorización 16/06/2025	Inicio de Ensayo 04/09/2025	Inclusión Primer Paciente 05/09/2025	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado
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Promotor

Astrazeneca Farmaceutica Spain S.A. Spain

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Contact Person

AstraZeneca Clinical Study Information Center

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (08/09/2025)	Complejo Hospitalario Universitario A Coruna A Coruna CORUÑA Hematology
Activo (21/01/2026)	Complejo Hospitalario Universitario De Vigo Vigo PONTEVEDRA Hematology
Activo (06/11/2025)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
Activo (04/09/2025)	Hospital General Universitario De Valencia Valencia VALENCIA Hematology
Activo (22/09/2025)	Hospital General Universitario Gregorio Maranon Madrid MADRID Hematology
Activo (13/10/2025)	Hospital Ruber Juan Bravo Madrid MADRID Hematology
Activo (04/09/2025)	Hospital Son Llatzer Palma BALEARES Hematology
Activo (04/09/2025)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology

Activo (04/09/2025)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

Activo (04/09/2025)

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Hematology

Activo (04/09/2025)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Activo (18/11/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (04/09/2025)

Hospital Universitario Donostia

Donostia

GUIPÚZCOA

Hematology

Activo (04/09/2025)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Activo (04/09/2025)

Hospital Universitario Fundacion Alcorcon

Alcorcon

MADRID

Hematology

Activo (21/11/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Activo (30/10/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (04/09/2025)

Hospital Universitario Nuestra Senora De Candelaria

Santa Cruz De Tenerife

STA. CRUZ DE TENERIFE

Hematology

Activo (31/10/2025)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Activo (04/09/2025)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Activo (04/09/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Calquence 100 mg film-coated tablets

FILM-COATED TABLET

ORAL

Código ATC: L01EL02 - ACALABRUTINIB

Principios Activos: N/A

Experimental

Sin resultados

A study to evaluate acalabrutinib, in combination with the R-CHOP standard of care, for previously untreated mantle cell lymphoma in Spain.

State
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase II

Expected Participants
55

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness

Advanced therapy
NO

Information

Identifier
2025-521152-34-00 (CTIS)

Protocol Code
D8220L00087

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

Investigated Disease
mantle cell lymphoma (MCL)

Scientific Title
The SOUND-MCL study: A single-arm, open-label, multicenter, phase II study of acalabrutinib, in combination with the R-CHOP standard of care, for previously untreated mantle cell lymphoma in Spain

Rationale

Not provided

Main Objective

To assess the efficacy in terms of treatment response to acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

Primary Endpoints

Investigator-assessed best ORR (CR+PR) as per the Lugano Classification for NHL. Timeframe: 1 year

Temporary moments of secondary assessment

Not provided

Secondary Objective

To further assess the efficacy of acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

To assess the safety and tolerability profile of acalabrutinib, in combination with the R-CHOP standard of care, in subjects with previously untreated MCL.

Secondary Endpoints

TTR, defined as the time from the date of acalabrutinib start to the first investigator-assessed CR or PR per the Lugano Classification for NHL. Measure of interest: median TTR.

DoR, defined as the time from the first documentation of investigator-assessed CR or PR to disease progression per the Lugano Classification for NHL or death from any cause in the absence of disease progression. Measure of interest: 30-month DoR

PFS, defined as the time from the date of acalabrutinib start to investigator-assessed disease progression as per the Lugano Classification for NHL or death from any cause, whichever occurs first. Measure of interest: 30-month PFS.

OS, defined as the time from the date of acalabrutinib start to the date of death from any cause. Measure of interest: 30-month OS

Describe the number and percentage of patients with each MedDRA coded and CTCAE graded adverse (AEs) and serious adverse events (SAEs).

Incidence of AEs of clinical interest for acalabrutinib.

Incidence of grade 3 AEs.

Incidence of AEs leading to acalabrutinib dose modification, temporary interruption or permanent discontinuation.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult (aged 18 years) men or women.

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Exclusion criteria

History of prior malignancy except for the following: a. Malignancy treated with curative intent and with no evidence of active disease present for more than 2 years before screening and felt to be at low risk for recurrence by treating physician. Note: Provided they meet other eligibility criteria, subjects who are receiving hormonal therapy alone are allowed to enroll on study. b. Adequately treated lentigo maligna melanoma without current evidence of disease or adequately controlled nonmelanomatous skin cancer. c. Adequately treated carcinoma in situ without current evidence of disease. History of stroke or intracranial hemorrhage within 6 months of first dose of study drug. History of bleeding diathesis (e.g., hemophilia or von Willebrand disease). Subjects for whom the goal of therapy is tumor debulking before stem cell transplant Presence of a gastrointestinal ulcer diagnosed by endoscopy within 3 months before first dose of study drug. Requires or receiving anticoagulation with warfarin or equivalent vitamin K antagonists (e.g., phenprocoumon) within 7 days of first dose of study drug. Requires treatment with a strong CYP3A inhibitor/inducer Concurrent participation in another therapeutic clinical trial. Active cytomegalovirus (CMV) infection (active viremia as evidenced by positive PCR result for CMV DNA). History of confirmed progressive multifocal leukoencephalopathy (PML). Any history of central nervous system (CNS) lymphoma or leptomeningeal disease Prothrombin time/international normalized ratio (INR) or activated partial thromboplastin time (aPTT) (in the absence

of a lupus anticoagulant) $>2.0 \times \text{ULN}$. Exception: Subjects receiving a vitamin K antagonist are excluded; however, those receiving other anticoagulant therapy who have a higher INR/aPTT may be permitted to enroll to this study after discussion with the medical monitor. Uncontrolled autoimmune hemolytic anemia (AIHA) or idiopathic thrombocytopenic purpura (ITP). Major surgical procedure within 28 days before first dose of study drug. Note: If a subject had major surgery, they must have recovered adequately from any toxicity and/or complications from the intervention before the first dose of study drug. Significant cardiovascular disease such as uncontrolled or untreated symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of first dose of study drug, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification at screening. Exception: Subjects with controlled, asymptomatic atrial fibrillation during screening are allowed to enroll on study. Absolute neutrophil count (ANC) $<1.0 \times 10^9/\text{L}$ or platelet count $<75 \times 10^9/\text{L}$; for subjects with disease involvement in the bone marrow, ANC $<0.75 \times 10^9/\text{L}$ or platelet count $<50 \times 10^9/\text{L}$. Subjects will only be considered eligible if peripheral blood counts can be maintained independent of growth factors or transfusions during the screening period. Total bilirubin $>1.5 \times$ upper limit normal (ULN) unless other reason known (e.g. Gilbert Syndrome, or due to lymphoma involvement); or aspartate aminotransferase (AST) or alanine transaminase (ALT) $>2.5 \times \text{ULN}$. Estimated creatinine clearance of $<30 \text{ mL/min}$, calculated using the formula of Cockcroft and Gault $[(140 - \text{age}) \text{ mass (kg)} / (72 \text{ creatinine mg/dL}) \text{ multiply by } 0.85 \text{ if female}]$. Subjects who are deemed by the treating physician to be unfit to tolerate the R-CHOP regimen. Pregnant or breastfeeding women. Malabsorption syndrome, disease significantly affecting gastrointestinal function, resection of the stomach, extensive small bowel resection that is likely to affect absorption, symptomatic inflammatory bowel disease, partial or complete bowel obstruction, or gastric restrictions and bariatric surgery, such as gastric bypass. Uncontrolled active systemic fungal, bacterial, viral, or other infection (defined as exhibiting ongoing signs/symptoms related to the infection and without improvement, despite appropriate antibiotics or other treatment), or intravenous anti-infective treatment within 2 weeks before first dose of study drug. Known history of infection with human immunodeficiency virus (HIV). Ongoing immunosuppressive therapy, including systemic (e.g., IV or oral) corticosteroids within 2 weeks before the first dose of study drug. Note: Subjects may use topical or inhaled corticosteroids or low-dose steroids (20 mg prednisone equivalent/day for 2 weeks) as a therapy for comorbid conditions and/or pre-phase treatment up to 100 mg/day or equivalent (for a maximum of 10 days prior to beginning study treatment) in participants with bulky disease, systemic symptoms, compressive disease, impaired liver function or cytopenias due to lymphoma, or rapidly progressing adenopathies. During study participation, subjects will receive corticosteroids as part of the R-CHOP regimen according to institution standards. Subjects may also receive systemic (e.g., IV or oral) corticosteroids as needed for treatment-emergent comorbid conditions. Known history of anaphylaxis or hypersensitivity to any study drug, or any of their components. Serologic status reflecting active hepatitis B or C infection. a. Subjects who are anti-HBc positive and who are surface antigen negative will need to have a negative polymerase chain reaction (PCR) result before the first dose of study drug. Those who are HbsAg positive or hepatitis B PCR positive will be excluded. b. Subjects who are hepatitis C antibody positive will need to have a negative PCR result before the first dose of study drug. Those who are hepatitis C PCR positive will be excluded. Received a live virus vaccination within 28 days of first dose of study drug.

Calendar

(Last Update: 19/06/2026)

Authorization 16/06/2025	Start of Trial 04/09/2025	First patient inclusion 05/09/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Astrazeneca Farmaceutica Spain S.A. Spain

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Contact Person

AstraZeneca Clinical Study Information Center

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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Burgos

BURGOS

Hematology

Active (04/09/2025)

Hospital Universitario De Cabuenes

Gijon

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Hematology

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Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Active (18/11/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (04/09/2025)

Hospital Universitario Donostia

Donostia

GUIPÚZCOA

Hematology

Active (04/09/2025)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Active (04/09/2025)

Hospital Universitario Fundacion Alcorcon

Alcorcon

MADRID

Hematology

Active (21/11/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Active (30/10/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (04/09/2025)

Hospital Universitario Nuestra Senora De Candelaria

Santa Cruz De Tenerife

STA. CRUZ DE TENERIFE

Hematology

Active (31/10/2025)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Active (04/09/2025)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Active (04/09/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Calquence 100 mg film-coated tablets

FILM-COATED TABLET

ORAL

ATC code: L01EL02 - ACALABRUTINIB

Active Principles: N/A

Experimental

No results