Seamless Phase 2/3 Study of Ibrutinib With Rituximab in Relapsed/Refractory Mantle Cell Lymphoma

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	23
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador

2023-503618-64-00 (CTIS)

Cod. Protocolo

54179060MCL3004

Transicionado 2022-000364-21

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Relapsed/Refractory Mantle Cell Lymphoma

Título Científico

A Randomized, Controlled, Open-label, Multicenter, Inferentially Seamless Phase 2/3 Study of Ibrutinib in Combination With Rituximab Versus Physicians Choice of Lenalidomide Plus Rituximab or Bortezomib Plus Rituximab in Participants with Relapsed or Refractory Mantle Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To provide continued access to study treatment for participants who continued to benefit from treatment

Variables de Evaluación Primaria

None

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

Adult patients with confirmed MCL
At least 1 prior treatment regimen for MCL excl. BTKi
Documented disease progression or relapse following the last anti-MCL treatment
Measurable nodal disease
ECOG 1
Adequate organ function: ANC 1000/mm3 Platelets 50,000 cells/mm3 Hemoglobin 8 g/dL ALT/AST 3 X ULN Total bilirubin 1.5 X ULN CrCl 30 mL/min
Must not be diagnosed or treated for malignancy other than MCL (with exceptions)
FOCBP and male participants with partners of childbearing potential must also comply with strict pregnancy prevention plan

Criterios de Exclusión

Prior therapy with BTKi Known history of HIV Active Hep B/C and E infection Prior therapy with both Lenalidomide and Bortezomib Major surgery within 4 weeks History of stroke or intracranial hemorrhage within 6 month prior to randomization Central nervous system lymphoma Bleeding disorder Clinically significant cardiovascular disease (e.g., uncontrolled arrhythmia, or Class II-IV congestive heart failure as defined by NYHA); or a history of MI, unstable angina, or acute coronary syndrome within 1 year prior to randomization (if >1 yr., a cardiology consultation documenting cardiac clearance is required) or uncontrolled HTN under treatment with 3 or more HTN medications, screening systolic BP>160 mm HG or diastolic BP>100mm Hg Anticancer therapy including chemotherapy, radiotherapy, small molecule, monoclonal antibody and investigational agents 21 days (or at least 5 drug half-lives, whichever is shorter) prior to first administration of study treatment Uncontrolled active systemic infection or any life-threatening illness, medical condition, or organ system dysfunction which, in the investigator's opinion, could compromise the participant's safety, or interfere with the absorption or metabolism of ibrutinib (including uncontrolled diabetes mellitus or HbA1C>7)

Calendario

(Última actualización: 09/04/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
26/10/2022	16/11/2022	23/01/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
10/05/2023	No aportado	No aportado	01/12/2023	26/09/2024

Promotor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CITIS 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

Cerrado (07/06/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Cerrado (22/02/2024)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Cerrado (29/05/2023)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Cerrado (16/06/2023)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Cerrado (05/07/2023)

Hospital Universitario Reina Sofia

Córdoba

CÓRDOBA

Medicamentos

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Experimental

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 2.5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Ruxience 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

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

Experimental

Lenalidomide Accord 20 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

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CAPSULE, HARD
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Experimental

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CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 2.5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

JNJ-54179060
CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Experimental

VELCADE 3.5 mg powder for solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS INJECTION

Código ATC: L01XG01 - BORTEZOMIB
Principios Activos: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Tiene resultados

Seamless Phase 2/3 Study of Ibrutinib With Rituximab in Relapsed/Refractory Mantle Cell Lymphoma

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	23
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2023-503618-64-00 (CTIS)

Protocol Code
54179060MCL3004

Transitioned 2022-000364-21

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

Investigated Disease
Relapsed/Refractory Mantle Cell Lymphoma

Scientific Title
A Randomized, Controlled, Open-label, Multicenter, Inferentially Seamless Phase 2/3 Study of Ibrutinib in Combination With Rituximab Versus Physicians Choice of Lenalidomide Plus Rituximab or Bortezomib Plus Rituximab in Participants with Relapsed or Refractory Mantle Cell Lymphoma

Rationale

Not provided

Main Objective

To provide continued access to study treatment for participants who continued to benefit from treatment

Primary Endpoints

None

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult patients with confirmed MCL
At least 1 prior treatment regimen for MCL excl. BTKi
Documented disease progression or relapse following the last anti-MCL treatment
Measurable nodal disease
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Calendar

(Last Update: 09/04/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
26/10/2022	16/11/2022	23/01/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
10/05/2023	Not aported	Not aported	01/12/2023	26/09/2024

Sponsor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CITIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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Closed (05/07/2023)

Hospital Universitario Reina Sofia

Córdoba

CÓRDOBA

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CAPSULE, HARD
ORAL USE

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

Experimental

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CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

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CAPSULE, HARD
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Active Principles: N/A

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CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Ruxience 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

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

Experimental

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CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

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ORAL USE

ATC code: L04AX04 - LENALIDOMIDA

Active Principles: N/A

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CAPSULE, HARD

ORAL USE

ATC code: L04AX04 - LENALIDOMIDA

Active Principles: N/A

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CAPSULE, HARD

ORAL USE

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Active Principles: N/A

Experimental

JNJ-54179060

CAPSULE, HARD

ORAL USE

-

Active Principles: N/A

Experimental

VELCADE 3.5 mg powder for solution for injection

SOLUTION FOR INJECTION

INTRAVENOUS INJECTION

ATC code: L01XG01 - BORTEZOMIB

Active Principles: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L04AX04 - LENALIDOMIDA

Active Principles: N/A

Experimental

Has results