EORTC 1820-CLTF: Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma (MOGAT)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	6
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador

2022-502434-10-00 (CTIS)

Cod. Protocolo

EORTC-1820-CLTF

Transicionado 2019-004566-17

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Cutaneous T-cell lymphoma (Mycosis Fungoides (MF)) and Sézary Syndrome (SS))
Cutaneous T-cell lymphoma, a category of cancers of lymphocytes (a type of white blood cells) that primarily involve the skin

Título Científico

EORTC 1820-CLTF: Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma (MOGAT)

Justificación

No aportado

Objetivo Principal

To evaluate the progression free survival rate at 48 weeks (according to EORTC-ISCL-USCLC criteria) of anti-CCR4 monoclonal antibody (mogamulizumab) and TSEB in IB-IIB cutaneous T-cell lymphoma.

Variables de Evaluación Primaria

Progression Free Survival Rate, at 48 weeks after start of mogamulizumab (PFSR-48).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the overall safety
To assess the response rate
To assess the progression-free survival
To assess the overall survival
To assess the time to progression
To evaluate the duration of response
To evaluate the time to next significant treatment

Variables de Evaluación Secundaria

Overall safety of both mogamulizumab and TSEB.
Response rate (RR) to both mogamulizumab and TSEB. Time Frame: From the first patient treatment start till 48 weeks as of last patient in Proportion of patients achieving partial response or complete response according to EORTC-ISCL-USCLC criteria
Progression-free survival (PFS). Overall survival (OS).
Time to progression. Duration of response.
Time to next treatment. Exploratory endpoints: Quality of life: Skindex-29 and EORTC-QLQ-C30, and time to treatment failure.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Males and female subjects 18 years
Mycosis fungoides stage IB, IIA, IIB
Subjects who have failed at least one prior course of systemic therapy. Psoralen plus ultraviolet light therapy (PUVA) is not considered to be a systemic therapy
Adequate haematological and organ function
Signed informed consent

Criterios de Exclusión

Prior treatment with mogamulizumab Known hypersensitivity to CHO cell products or any component of the mogamulizumab formulation Significant uncontrolled intercurrent illness Prior TSEB treatment with at least one of the following conditions: Patient has received high-dose TSEB (>30 Gray) Patient has received TSEB ((including low-dose [12 Gray]) within 12 months before enrolment

Calendario

(Última actualización: 06/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
08/10/2021	21/02/2023	09/05/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
03/07/2026	No aportado	No aportado	No aportado	No aportado

Promotor

European Organisation For Research And Treatment Of Cancer Belgium

Emmanuel Mounierlaan 83/11

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Cerrado (15/02/2024)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Activo (01/03/2023)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Activo (21/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medicamentos

-

-

INTRAVENOUS

Código ATC: L01XC25 - MOGAMULIZUMAB

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

EORTC 1820-CLTF: Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma (MOGAT)

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	6
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2022-502434-10-00 (CTIS)

Protocol Code
EORTC-1820-CLTF

Transitioned 2019-004566-17

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

Investigated Disease
Cutaneous T-cell lymphoma (Mycosis Fungoides (MF)) and Sézary Syndrome (SS))
Cutaneous T-cell lymphoma, a category of cancers of lymphocytes (a type of white blood cells) that primarily involve the skin

Scientific Title

EORTC 1820-CLTF: Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma (MOGAT)

Rationale

Not provided

Main Objective

To evaluate the progression free survival rate at 48 weeks (according to EORTC-ISCL-USCLC criteria) of anti-CCR4 monoclonal antibody (mogamulizumab) and TSEB in IB-IIB cutaneous T-cell lymphoma.

Primary Endpoints

Progression Free Survival Rate, at 48 weeks after start of mogamulizumab (PFSR-48).

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the overall safety
To assess the response rate
To assess the progression-free survival
To assess the overall survival
To assess the time to progression
To evaluate the duration of response
To evaluate the time to next significant treatment

Secondary Endpoints

Overall safety of both mogamulizumab and TSEB.
Response rate (RR) to both mogamulizumab and TSEB. Time Frame: From the first patient treatment start till 48 weeks as of last patient in Proportion of patients achieving partial response or complete response according to EORTC-ISCL-USCLC criteria
Progression-free survival (PFS). Overall survival (OS).
Time to progression. Duration of response.
Time to next treatment. Exploratory endpoints: Quality of life: Skindex-29 and EORTC-QLQ-C30, and time to treatment failure.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Males and female subjects 18 years
Mycosis fungoides stage IB, IIA, IIB
Subjects who have failed at least one prior course of systemic therapy. Psoralen plus ultraviolet light therapy (PUVA) is not considered to be a systemic therapy
Adequate haematological and organ function
Signed informed consent

Exclusion criteria

Prior treatment with mogamulizumab Known hypersensitivity to CHO cell products or any component of the mogamulizumab formulation Significant uncontrolled intercurrent illness Prior TSEB treatment with at least one of the following conditions: Patient has received high-dose TSEB (>30 Gray) Patient has received TSEB ((including low-dose [12 Gray]) within 12 months before enrolment

Calendar

(Last Update: 06/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
08/10/2021	21/02/2023	09/05/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
03/07/2026	Not aported	Not aported	Not aported	Not aported

Sponsor

European Organisation For Research And Treatment Of Cancer Belgium

Emmanuel Mounierlaan 83/11

Contact Person

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vassilis.golfinopoulos@eortc.org

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario 12 de Octubre

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Sites

Closed (15/02/2024)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Active (01/03/2023)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Active (21/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medication

-

-

INTRAVENOUS

ATC code: L01XC25 - MOGAMULIZUMAB

Active Principles: N/A

Orphan **Experimental**

No results