EORTC-1537-LYMG: Very early FDG-PET-response adapted targeted therapy for advanced Hodgkin lymphoma: a single-arm phase II study

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	7
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	tratamiento, seguridad, eficacia	NO

Información

Identificador

2023-508478-27-00 (CTIS)

Cod. Protocolo

1537-LYMG

Transicionado 2017-000498-35

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Advanced stage Hodgkin Lymphoma

Título Científico

EORTC-1537-LYMG: Very early FDG-PET-response adapted targeted therapy for advanced Hodgkin lymphoma: a single-arm phase II study

Justificación

No aportado

Objetivo Principal

The main objective of this trial is to assess whether treatment adaptation based on a very early FDG-PET/CT results in improved efficacy while minimizing treatment toxicity in advanced stage HL patients treated with BV-containing regimens, BrAVD and BrECADD. This will be primarily assessed by modified progression-free survival.

Variables de Evaluación Primaria

Modified progression-free survival rate at 2 years after start of treatment (2yr-mPFS for each patient). The following are considered events for the primary endpoint: progression/relapse; start of new treatment for cHL when not in CR after completing protocol treatment; death from any cause.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the rate of FDG-PET negativity (Deauville score 1-3) after 1 cycle of BrAVD
To assess response according to Lugano Criteria at end of protocol treatment i.e. after chemotherapy and after radiotherapy (if administered), as defined by FDG-PET/CT
To assess the safety and tolerability of the different BV containing regimens
To assess the safety and tolerability of radiotherapy in the context of BrAVD and BrECADD
To assess efficacy in terms of PFS and OS

Variables de Evaluación Secundaria

FDG-PET result (positive/negative) after 1 cycle of BrAVD (central assessment)
Response according to Lugano Criteria at end of protocol treatment i.e. after chemotherapy and after radiotherapy (if administered), as defined by FDG-PET/CT
Progression-free survival (where progression, relapse and death from any cause are considered events)
Overall survival
Safety and tolerability
Response according to RECIL 2017

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Previously untreated, histologically proven classical Hodgkin lymphoma Absence of any medical, psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations Staged by PET with diagnostic-quality CT (i.v. contrast). - Clinical stages according to Lugano 2014 and based on FDG/PET CT:Stage IIB with large mediastinal mass > 1/3 max transverse diameter thorax and/or extranodal lesion(s) (GHSG) - Stage III - IV Participation in translational research is mandatory and therefore patient must consent to additional blood samples at multiple time points in the study. In addition, sufficient tissue must be available (15 blank formalin fixed paraffin embedded tissue samples mounted on APES slides or a tissue block) Age 18 and 60 WHO performance status 0-2 Patient demonstrates adequate organ function as defined in the protocol Women of child bearing potential (WOCBP) must have a negative serum pregnancy test within 72 hours prior to the first dose of study treatment Patients of childbearing / reproductive potential should use two birth control methods, as defined by the investigator, from the time of signing the informed consent form, and throughout the entire study and for 6 months after the last dose of treatment Female subjects who are breast feeding should discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment

Criterios de Exclusión

Known cerebral or meningeal disease (HL or any other etiology), including signs or symptoms of Progressive Multifocal Leukoencenphalopathy Myocardial infarction Patients with poorly controlled diabetes mellitus (HbA1c > 7.5 % or a fasting blood sugar > 200 mg/dL) Any active systemic viral, bacterial, or fungal infection requiring systemic antibiotics within 2 weeks prior to registration Known HIV infection, chronic active hepatitis C, HBV positivity (HBsAg + patients; HBsAg -/HBcAb+/HBV DNA+ patients) Concomitant or previous malignancies within the past 5 years with the exception of adequately treated carcinoma in situ of the cervix, nonmelanoma skin cancer Previous treatment with anti CD30 antibodies Known hypersensitivity to any excipient contained in Brentuximab Vedotin formulation and other study drugs Concurrent anti-cancer treatment or use of any investigational agent(s) Symptomatic neurologic disease compromising normal activities of daily living or requiring medications Sensory or motor peripheral neuropathy greater than or equal to grade 2 according to CTCAE version 5.0 Any of the following cardiovascular conditions or values: - within 6 months before registration A left-ventricular ejection fraction <50% New York Heart Association (NYHA) Class III or IV heart failure Evidence of current uncontrolled cardiovascular conditions, including cardiac arrhythmias, congestive heart failure (CHF), angina, or electrocardiographic evidence of acute ischemia or active conduction system abnormalities symptomatic coronary heart disease (stable angina pectoris is allowed) severe uncontrolled hypertension defined as blood pressure (BP) >150/100 mmHg despite optimal antihypertensive treatment - within 2 years before registration

Calendario

(Última actualización: 11/11/2024)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/06/2019	16/09/2019	26/09/2019	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
17/08/2021	No aportado	No aportado	No aportado	No aportado

Promotor

European Organisation For Research And Treatment Of Cancer Belgium

Emmanuel Mounierlaan 83 Bus 11

Contact Person

Vassilis Golfinopoulos

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

mcruz@idibell.cat

Centros

Activo (29/10/2019)

COMPLEJO HOSPITALARIO A (ANTIGUO HOSPITAL DE NAVARRA)*

Pamplona/Iruña

NAVARRA

Hematology

No iniciado (--/--/----)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Activo (16/09/2019)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematology

Medicamentos

-
-
INFUSION

Código ATC: L01AX04 - DACARBAZINA
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: S02BA06 - DEXAMETASONA
Principios Activos: N/A

Experimental

-
-
INFUSION

Código ATC: L01CB01 - ETOPOSIDO
Principios Activos: N/A

Experimental

-
-
INFUSION

Código ATC: L01CA01 - VINBLASTINA
Principios Activos: N/A

Experimental

-
-
INFUSION

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A

Experimental

ADCETRIS 50 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INFUSION

Código ATC: L01XC12 - BRENTUXIMAB VEDOTINA
Principios Activos: N/A

Experimental

-
-
INFUSION

Código ATC: L01DB01 - DOXORUBICINA
Principios Activos: N/A

Experimental

Sin resultados

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State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	7
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	treatment, safety, effectiveness	NO

Information

Identifier
2023-508478-27-00 (CTIS)

Protocol Code
1537-LYMG

Transitioned 2017-000498-35

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

Investigated Disease
Advanced stage Hodgkin Lymphoma

Scientific Title
EORTC-1537-LYMG: Very early FDG-PET-response adapted targeted therapy for advanced Hodgkin lymphoma: a single-arm phase II study

Rationale

Not provided

Main Objective

The main objective of this trial is to assess whether treatment adaptation based on a very early FDG-PET/CT results in improved efficacy while minimizing treatment toxicity in advanced stage HL patients treated with BV-containing regimens, BrAVD and BrECADD. This will be primarily assessed by modified progression-free survival.

Primary Endpoints

Modified progression-free survival rate at 2 years after start of treatment (2yr-mPFS for each patient). The following are considered events for the primary endpoint: progression/relapse; start of new treatment for cHL when not in CR after completing protocol treatment; death from any cause.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the rate of FDG-PET negativity (Deauville score 1-3) after 1 cycle of BrAVD
To assess response according to Lugano Criteria at end of protocol treatment i.e. after chemotherapy and after radiotherapy (if administered), as defined by FDG-PET/CT
To assess the safety and tolerability of the different BV containing regimens
To assess the safety and tolerability of radiotherapy in the context of BrAVD and BrECADD
To assess efficacy in terms of PFS and OS

Secondary Endpoints

FDG-PET result (positive/negative) after 1 cycle of BrAVD (central assessment)
Response according to Lugano Criteria at end of protocol treatment i.e. after chemotherapy and after radiotherapy (if administered), as defined by FDG-PET/CT
Progression-free survival (where progression, relapse and death from any cause are considered events)
Overall survival
Safety and tolerability
Response according to RECIL 2017

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Previously untreated, histologically proven classical Hodgkin lymphoma Absence of any medical, psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations Staged by PET with diagnostic-quality CT (i.v. contrast). - Clinical stages according to Lugano 2014 and based on FDG/PET CT:Stage IIB with large mediastinal mass > 1/3 max transverse diameter thorax and/or extranodal lesion(s) (GHSG) - Stage III - IV Participation in translational research is mandatory and therefore patient must consent to additional blood samples at multiple time points in the study. In addition, sufficient tissue must be available (15 blank formalin fixed paraffin embedded tissue samples mounted on APES slides or a tissue block) Age 18 and 60 WHO performance status 0-2 Patient demonstrates adequate organ function as defined in the protocol Women of child bearing potential (WOCBP) must have a negative serum pregnancy test within 72 hours prior to the first dose of study treatment Patients of childbearing / reproductive potential should use two birth control methods, as defined by the investigator, from the time of signing the informed consent form, and throughout the entire study and for 6 months after the last dose of treatment Female subjects who are breast feeding should discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment

Exclusion criteria

Known cerebral or meningeal disease (HL or any other etiology), including signs or symptoms of Progressive Multifocal Leukoencenphalopathy Myocardial infarction Patients with poorly controlled diabetes mellitus (HbA1c > 7.5 % or a fasting blood sugar > 200 mg/dL) Any active systemic viral, bacterial, or fungal infection requiring systemic antibiotics within 2 weeks prior to registration Known HIV infection, chronic active hepatitis C, HBV positivity (HBsAg + patients; HBsAg -/HBcAb+/HBV DNA+ patients) Concomitant or previous malignancies within the past 5 years with the exception of adequately treated carcinoma in situ of the cervix, nonmelanoma skin cancer Previous treatment with anti CD30 antibodies Known hypersensitivity to any excipient contained in Brentuximab Vedotin formulation and other study drugs Concurrent anti-cancer treatment or use of any investigational agent(s) Symptomatic neurologic disease compromising normal activities of daily living or requiring medications Sensory or motor peripheral neuropathy greater than or equal to grade 2 according to CTCAE version 5.0 Any of the following cardiovascular conditions or values: - within 6 months before registration A left-ventricular ejection fraction <50% New York Heart Association (NYHA) Class III or IV heart failure Evidence of current uncontrolled cardiovascular conditions, including cardiac arrhythmias, congestive heart failure (CHF), angina, or electrocardiographic evidence of acute ischemia or active conduction system abnormalities symptomatic coronary heart disease (stable angina pectoris is allowed) severe uncontrolled hypertension defined as blood pressure (BP) >150/100 mmHg despite optimal antihypertensive treatment - within 2 years before registration

Calendar

(Last Update: 11/11/2024)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/06/2019	16/09/2019	26/09/2019	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
17/08/2021	Not aported	Not aported	Not aported	Not aported

Sponsor

European Organisation For Research And Treatment Of Cancer Belgium

Emmanuel Mounierlaan 83 Bus 11

Contact Person

Vassilis Golfinopoulos

+3227741665

vassilis.golfinopoulos@eortc.org

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

mcruz@idibell.cat

Sites

Active (29/10/2019)

COMPLEJO HOSPITALARIO A (ANTIGUO HOSPITAL DE NAVARRA)*

Pamplona/Iruña

NAVARRA

Hematology

not initialized (--/--/----)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Active (16/09/2019)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematology

Medication

-
-
INFUSION

ATC code: L01AX04 - DACARBAZINA
Active Principles: N/A

Experimental

-
-
ORAL

ATC code: S02BA06 - DEXAMETASONA
Active Principles: N/A

Experimental

-
-
INFUSION

ATC code: L01CB01 - ETOPOSIDO
Active Principles: N/A

Experimental

-
-
INFUSION

ATC code: L01CA01 - VINBLASTINA
Active Principles: N/A

Experimental

-
-
INFUSION

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A

Experimental

ADCETRIS 50 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INFUSION

ATC code: L01XC12 - BRENTUXIMAB VEDOTINA
Active Principles: N/A

Experimental

-
-
INFUSION

ATC code: L01DB01 - DOXORUBICINA
Active Principles: N/A

Experimental

No results