RADAR: A randomised phase III trial with a PET response adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in patients with previously untreated stage IA/IIA Hodgkin lymphoma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	342
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2022-500031-37-00 (CTIS)

Cod. Protocolo
UCL/15/0105

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

Enfermedad investigada
stage IA/IIA Hodgkin lymphoma

Título Científico
RADAR: A randomised phase III trial with a PET response adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in patients with previously untreated stage IA/IIA Hodgkin lymphoma

Justificación

phase III trial<br/

Objetivo Principal

To assess whether substituting A2VD for ABVD as part of a PET-response adapted design in early stage HL can: improve the Progression Free Survival (PFS)

Variables de Evaluación Primaria

Progression-Free Survival (PFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Prognostic value of baseline metabolic tumour volume and/or tumour lesion glycolysis on PET
Prognostic power of PET after 1 & 2 cycles of ABVD/A2VD compared with EORTC and GHSG pre-treatment risk factors
Prognostic power of PET after 1 and 2 cycles using a quantitative extension to the Deauville score
Correlate response to treatment and side-effects with radiomic features on PET-CT
Evaluate the use of automated methods to measure uptake in and segment tumour and non-tumour tissue on FDG PET-CT scans
Change in pulmonary function tests
Relationship between maximum tumour dimension at baseline and end of treatment with PFS
Improve the PET Complete Metabolic Response (CMR) rate
Improve the Overall Survival (OS)
Decrease the late toxicity by reducing the proportion of patients receiving radiotherapy (RT) and the incidence of second cancers and cardiovascular disease
Improve Event Free Survival (EFS)

Variables de Evaluación Secundaria

PET Complete Metabolic Response (CMR) rate after 2 cycles of ABVD/ A2VD
Event-Free Survival (EFS)
Overall survival (OS)
Incidence of second cancers and cardiovascular disease
Safety and toxicity of ABVD and A2VD as assessed by CTCAE v5.0

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Males and females age 16-69 years (inclusive). Adequate bone marrow function with neutrophils 1.0x10exp9/l and platelets 100 x10exp9/l Haemoglobin 80 g/L (equivalent to 4.96mmol/L) Willing and able to comply with the requirements of the protocol, including contraceptive advice, where applicable Written informed consent Histologically confirmed classical Hodgkin lymphoma Stage I or II supradiaphragmatic disease with no mediastinal bulk disease (defined as greater than a third of the transthoracic diameter at any level of thoracic vertebrae as determined by CT) or B symptoms. Bulky disease at other sites is acceptable. Extranodal disease (single extranodal site (stage I) or contiguous extranodal extension (stage II)) is acceptable. ECOG performance status 0-2 No previous treatment for Hodgkin lymphoma Fit to receive anthracycline based chemotherapy (patients with a history of ischaemic heart disease or hypertension should have a left ventricular ejection fraction of 50%) Creatinine clearance (measured or calculated) >40 ml/min Total bilirubin < 1.5 x upper limit of normal, unless attributable to disease or known Gilberts syndrome ALT or AST < 2 x the upper limit of normal

Criterios de Exclusión

Previous treatment for Hodgkin lymphoma, excluding short courses of oral corticosteroids at a dose of up to 100mg prednisolone (or equivalent) for up to 7 days Nodular lymphocyte predominant Hodgkin lymphoma Absence of FDG-avid lymphoma lesions on baseline PET scan Age 70 years or over, or 17 years and under Other active cancer (new, relapsed or persistent) within the last 5 years with the exception of: a) Prostate cancer meeting the following criteria: Gleason grade group 1 (Gleason score 6) being managed with active surveillance. Previously treated more than 1 year ago with radical prostatectomy and undetectable PSA, or definitive radiation therapy and PSA <2 and stable or falling. b) Skin cancers meeting the following criteria: Completely excised carcinoma in situ of any type and basal or squamous cell carcinoma of the skin c.) Other cancers meeting the following criteria: Treated 5 or more years ago with no recurrence since that time Pre-existing sensory or motor peripheral neuropathy from any cause, grade 1 History of or current progressive multi-focal leukoencephalopathy Known infection with HIV, hepatitis C or active hepatitis B infection (surface antigen or DNA positive) Any active systemic viral, bacterial, or fungal infection requiring systemic antibiotics, antivirals or antifungals within 2 weeks prior to first study drug dose Receiving or recently treated with any other investigational agent (within 4 weeks of study entry) Pregnant or breastfeeding women Known hypersensitivity to recombinant proteins, murine proteins, or to any excipient contained in the drug formulation of brentuximab vedotin or any component of ABVD Known history of any cardiovascular or respiratory conditions that would preclude anthracycline or bleomycin administration Other significant medical or psychiatric co-morbidity that in the opinion of the investigator would make administration of ABVD or A2VD hazardous Infradiaphragmatic disease

Calendario

(Última actualización: 17/06/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/07/2023	18/04/2024	23/04/2024	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

University College London United Kingdom

Gower Street

Contact Person

Nick McNally

02073809995

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

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

Hospital Del Mar

Barcelona

BARCELONA

hematology

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

Hospital Universitario De Navarra

Pamplona

NAVARRA

hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

hematology

Medicamentos

-
-
SUBCUTANEOUS

Código ATC: L03AA02 - FILGRASTIM
Principios Activos: N/A

Experimental

Bleomycin 15000 IU Powder for solution for injection/ infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Código ATC: L01DC01 - BLEOMICINA
Principios Activos: N/A

Experimental

Dacarbazine medac 500 mg, powder for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

Dacarbazine medac 100 mg, powder for solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

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

Experimental

Vinblastine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS

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

Experimental

Dacarbazine medac 200 mg, powder for solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

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

Experimental

Doxorubicin hydrochloride 2 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

Dacarbazine medac 1000 mg, powder for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

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

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

Huérfano **Experimental**

Sin resultados

RADAR: A randomised phase III trial with a PET response adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in patients with previously untreated stage IA/IIA Hodgkin lymphoma

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	342
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2022-500031-37-00 (CTIS)

Protocol Code
UCL/15/0105

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

Investigated Disease
stage IA/IIA Hodgkin lymphoma

Scientific Title
RADAR: A randomised phase III trial with a PET response adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in patients with previously untreated stage IA/IIA Hodgkin lymphoma

Rationale

phase III trial<br/

Main Objective

To assess whether substituting A2VD for ABVD as part of a PET-response adapted design in early stage HL can: improve the Progression Free Survival (PFS)

Primary Endpoints

Progression-Free Survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Prognostic value of baseline metabolic tumour volume and/or tumour lesion glycolysis on PET
Prognostic power of PET after 1 & 2 cycles of ABVD/A2VD compared with EORTC and GHSG pre-treatment risk factors
Prognostic power of PET after 1 and 2 cycles using a quantitative extension to the Deauville score
Correlate response to treatment and side-effects with radiomic features on PET-CT
Evaluate the use of automated methods to measure uptake in and segment tumour and non-tumour tissue on FDG PET-CT scans
Change in pulmonary function tests
Relationship between maximum tumour dimension at baseline and end of treatment with PFS
Improve the PET Complete Metabolic Response (CMR) rate
Improve the Overall Survival (OS)
Decrease the late toxicity by reducing the proportion of patients receiving radiotherapy (RT) and the incidence of second cancers and cardiovascular disease
Improve Event Free Survival (EFS)

Secondary Endpoints

PET Complete Metabolic Response (CMR) rate after 2 cycles of ABVD/ A2VD
Event-Free Survival (EFS)
Overall survival (OS)
Incidence of second cancers and cardiovascular disease
Safety and toxicity of ABVD and A2VD as assessed by CTCAE v5.0

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Males and females age 16-69 years (inclusive). Adequate bone marrow function with neutrophils 1.0x10exp9/l and platelets 100 x10exp9/l Haemoglobin 80 g/L (equivalent to 4.96mmol/L) Willing and able to comply with the requirements of the protocol, including contraceptive advice, where applicable Written informed consent Histologically confirmed classical Hodgkin lymphoma Stage I or II supradiaphragmatic disease with no mediastinal bulk disease (defined as greater than a third of the transthoracic diameter at any level of thoracic vertebrae as determined by CT) or B symptoms. Bulky disease at other sites is acceptable. Extranodal disease (single extranodal site (stage I) or contiguous extranodal extension (stage II)) is acceptable. ECOG performance status 0-2 No previous treatment for Hodgkin lymphoma Fit to receive anthracycline based chemotherapy (patients with a history of ischaemic heart disease or hypertension should have a left ventricular ejection fraction of 50%) Creatinine clearance (measured or calculated) >40 ml/min Total bilirubin < 1.5 x upper limit of normal, unless attributable to disease or known Gilberts syndrome ALT or AST < 2 x the upper limit of normal

Exclusion criteria

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Calendar

(Last Update: 17/06/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/07/2023	18/04/2024	23/04/2024	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

University College London United Kingdom

Gower Street

Contact Person

Nick McNally

02073809995

Ctc.sponsor@ucl.ac.uk

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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

Hospital Del Mar

Barcelona

BARCELONA

hematology

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

Hospital Universitario De Navarra

Pamplona

NAVARRA

hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

hematology

Medication

-
-
SUBCUTANEOUS

ATC code: L03AA02 - FILGRASTIM
Active Principles: N/A

Experimental

Bleomycin 15000 IU Powder for solution for injection/ infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

ATC code: L01DC01 - BLEOMICINA
Active Principles: N/A

Experimental

Dacarbazine medac 500 mg, powder for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

Dacarbazine medac 100 mg, powder for solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

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

Experimental

Vinblastine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS

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

Experimental

Dacarbazine medac 200 mg, powder for solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

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

Experimental

Doxorubicin hydrochloride 2 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

Dacarbazine medac 1000 mg, powder for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

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

Experimental

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

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

Orphan **Experimental**

No results