Clinical trial for the use of a humanized CART directed against BCMA (ARI0002h) in patients with newly diagnosed primary plasma cell leukemia.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	25
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2024-515053-21-00 (CTIS)

Cod. Protocolo
GEM-PLASMACAR

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

Enfermedad investigada
Plasma cell leukaemia

Título Científico
Phase II, multicenter, open-label, prospective, non-randomized study to evaluate the safety and efficacy of ARI0002h, a CAR-T cell against BCMA, for the initial treatment of patients with primary plasma cell leukaemia

Justificación

No aportado

Objetivo Principal

To assess the safety and efficacy of CARTBCMA ARI0002h (Cesnicabtagene autoleucel) after initial treatment to induce response in patients with newly diagnosed primary plasma cell leukaemia.

Variables de Evaluación Primaria

Primary efficacy endpoints: Overall response rate (ORR) during the first 3 months after the first infusion (at least partial response according to the International Myeloma Working Group criteria)
Primary safety endpoint: Rate of patients who develop a cytokine release syndrome and/or neurological toxicity in the first 30 days after CARTBCMA administration, according to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Evaluating the efficacy of ARI0002h
Assessing the duration of response after administration of ARI0002h
Evaluating the overall survival after the administration of ARI0002h
Evaluating the persistence of ARI0002h cells in peripheral blood after their administration
Evaluating the effect of treatment with ARI0002h on the quality of life of patient during the first year
Assessing adverse events occurring at 3 months and 1 year

Variables de Evaluación Secundaria

Duration of response calculated from the time of first disease evaluation (day +28 after infusion) for those patients who achieved at least partial response.
Response rates during the first year.
Complete response rate (CR) at 3, 6, and 12 months after the first infusion.
Overall response rate at 6, and 12 months after the first infusion.
Time to complete response.
Time to best response.
MRD negative rate in bone marrow by flow cytometry at 3, 6 12 and 24 months.
Response rate of extramedullary disease by PET-CT at 3 and 12 months.
Progression-free survival, defined as the time between administration of ARI0002h and disease progression or death. Patients who are alive and in complete remission will be censored at the time of the last follow-up.
Progression-free survival at 12 months after the first administration, defined as the time elapsed between the

administration of ARI0002h and disease progression or death. Patients who are alive and in complete remission will be censored at the time of the last follow-up.
Overall survival (OS), defined as the time between infusion of ARI0002h and death of the patient from any cause. Living patients will be censored at the time of last follow-up.
Presence of infusion reactions, understood as the appearance of any of the following symptoms after the intravenous administration of CARTBCMA: cardiac events, chills, dyspnoea, fatigue, sudden hypertension, hypotension, nausea, pain, fever, rash or urticaria.
Tumour lysis syndrome at any time after treatment administration.
Cytokine release syndrome. According to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019).
Neurological toxicity (According to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019)).
Presence of prolonged cytopenias, defined as a grade 4 decrease in peripheral blood neutrophil or platelet counts for more than 4 weeks after infusion.
Quality of life during the first two years after infusion according to the 2009 EuroQol Group EQ-5D-5L questionnaire.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients between 18 and 75 years old diagnosed with newly diagnosed primary plasma cell leukemia (the presence of 5% or more circulating plasma cells in peripheral blood smears in patients otherwise diagnosed with symptomatic multiple myeloma), according to International Myeloma Working Group (IMWG). In order to confirm this inclusion criteria, two peripheral blood slides of the diagnostic will be sent to the coordinating team at HCB. In the event that a diagnostic slide is unavailable, a document confirming the diagnostic results must be provided instead.
Disease measurable at diagnosis by monoclonal component in serum or urine, or by free light chains in serum according to the eligibility criteria for clinical trials of the "International Myeloma Working Group".
ECOG Performance Status from 0 to 1
Life expectancy greater than 3 months
Adequate venous access and absence of contraindications for lymphoapheresis
Patients who, after being informed, give their consent by signing the Informed Consent Document.

Criterios de Exclusión

No previous treatments, except for induction therapy for primary plasma cell leukemia. Severe organ impairment that meets any of the following criteria: EF<40%, DLCO <40%, GFR <30 ml/min, bilirubin >3 times the upper limit of normality (unless due to Gilbert syndrome). Previous diagnosis of symptomatic AL amyloidosis. Pregnant or lactating women. Women of childbearing potential must have a negative pregnancy test at the screening phase. Women of childbearing potential, including those whose last menstrual cycle was in the year prior to screening, who are unable or unwilling to use highly effective contraceptive methods from the beginning of the study to completion of the study. Men who are unable or unwilling to use highly effective contraceptive methods from the beginning of the study to completion of the study. Contraindication to receive lymphodepletive chemotherapy. Administration of any anti-BCMA therapy as part of induction Not having achieved at least a minimal response with induction treatment (IMWG criteria) Absolute lymphocyte count <0.1x109/L Active immunosuppressive therapy except for prednisone 10 mg/day (or equivalent) Any other concomitant neoplasia, unless it has been in complete remission for 3 years or longer, except for non-melanoma skin cancer or completely resected in situ carcinoma. Active infection requiring treatment. Active HIV, HBV, or HCV infection. Uncontrolled medical illness.

Calendario

(Última actualización: 27/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
10/03/2025	30/04/2025	01/07/2025	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

Fundacio De Recerca Clinic Barcelona-Institut D¿Investigacions Biomediques August Pi I Sunyer Spain

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Contact Person

Clinical Trials Unit

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (30/04/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (30/07/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (01/09/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (19/05/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (26/05/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

Cesnicabtagene autoleucel
DISPERSION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

FLUDARABINE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL

-
Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

PARACETAMOL
TABLET
ORAL

-
Principios Activos: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: R06A - ANTIHISTAMINICOS PARA USO SISTEMICO
Principios Activos: N/A

Experimental

Sin resultados

Clinical trial for the use of a humanized CART directed against BCMA (ARI0002h) in patients with newly diagnosed primary plasma cell leukemia.

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	25
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2024-515053-21-00 (CTIS)

Protocol Code
GEM-PLASMACAR

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

Investigated Disease
Plasma cell leukaemia

Scientific Title
Phase II, multicenter, open-label, prospective, non-randomized study to evaluate the safety and efficacy of ARI0002h, a CAR-T cell against BCMA, for the initial treatment of patients with primary plasma cell leukaemia

Rationale

Not provided

Main Objective

To assess the safety and efficacy of CARTBCMA ARI0002h (Cesnicabtagene autoleucel) after initial treatment to induce response in patients with newly diagnosed primary plasma cell leukaemia.

Primary Endpoints

Primary efficacy endpoints: Overall response rate (ORR) during the first 3 months after the first infusion (at least partial response according to the International Myeloma Working Group criteria)
Primary safety endpoint: Rate of patients who develop a cytokine release syndrome and/or neurological toxicity in the first 30 days after CARTBCMA administration, according to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019).

Temporary moments of secondary assessment

Not provided

Secondary Objective

Evaluating the efficacy of ARI0002h
Assessing the duration of response after administration of ARI0002h
Evaluating the overall survival after the administration of ARI0002h
Evaluating the persistence of ARI0002h cells in peripheral blood after their administration
Evaluating the effect of treatment with ARI0002h on the quality of life of patient during the first year
Assessing adverse events occurring at 3 months and 1 year

Secondary Endpoints

Duration of response calculated from the time of first disease evaluation (day +28 after infusion) for those patients who achieved at least partial response.
Response rates during the first year.
Complete response rate (CR) at 3, 6, and 12 months after the first infusion.
Overall response rate at 6, and 12 months after the first infusion.
Time to complete response.
Time to best response.
MRD negative rate in bone marrow by flow cytometry at 3, 6 12 and 24 months.
Response rate of extramedullary disease by PET-CT at 3 and 12 months.
Progression-free survival, defined as the time between administration of ARI0002h and disease progression or death. Patients who are alive and in complete remission will be censored at the time of the last follow-up.
Progression-free survival at 12 months after the first administration, defined as the time elapsed between the

administration of ARI0002h and disease progression or death. Patients who are alive and in complete remission will be censored at the time of the last follow-up.
Overall survival (OS), defined as the time between infusion of ARI0002h and death of the patient from any cause. Living patients will be censored at the time of last follow-up.
Presence of infusion reactions, understood as the appearance of any of the following symptoms after the intravenous administration of CARTBCMA: cardiac events, chills, dyspnoea, fatigue, sudden hypertension, hypotension, nausea, pain, fever, rash or urticaria.
Tumour lysis syndrome at any time after treatment administration.
Cytokine release syndrome. According to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019).
Neurological toxicity (According to the criteria and grading defined in the international consensus document (Lee, Santomasso et al. 2019)).
Presence of prolonged cytopenias, defined as a grade 4 decrease in peripheral blood neutrophil or platelet counts for more than 4 weeks after infusion.
Quality of life during the first two years after infusion according to the 2009 EuroQol Group EQ-5D-5L questionnaire.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients between 18 and 75 years old diagnosed with newly diagnosed primary plasma cell leukemia (the presence of 5% or more circulating plasma cells in peripheral blood smears in patients otherwise diagnosed with symptomatic multiple myeloma), according to International Myeloma Working Group (IMWG). In order to confirm this inclusion criteria, two peripheral blood slides of the diagnostic will be sent to the coordinating team at HCB. In the event that a diagnostic slide is unavailable, a document confirming the diagnostic results must be provided instead.
Disease measurable at diagnosis by monoclonal component in serum or urine, or by free light chains in serum according to the eligibility criteria for clinical trials of the "International Myeloma Working Group".
ECOG Performance Status from 0 to 1
Life expectancy greater than 3 months
Adequate venous access and absence of contraindications for lymphoapheresis
Patients who, after being informed, give their consent by signing the Informed Consent Document.

Exclusion criteria

No previous treatments, except for induction therapy for primary plasma cell leukemia. Severe organ impairment that meets any of the following criteria: EF<40%, DLCO <40%, GFR <30 ml/min, bilirubin >3 times the upper limit of normality (unless due to Gilbert syndrome). Previous diagnosis of symptomatic AL amyloidosis. Pregnant or lactating women. Women of childbearing potential must have a negative pregnancy test at the screening phase. Women of childbearing potential, including those whose last menstrual cycle was in the year prior to screening, who are unable or unwilling to use highly effective contraceptive methods from the beginning of the study to completion of the study. Men who are unable or unwilling to use highly effective contraceptive methods from the beginning of the study to completion of the study. Contraindication to receive lymphodepletive chemotherapy. Administration of any anti-BCMA therapy as part of induction Not having achieved at least a minimal response with induction treatment (IMWG criteria) Absolute lymphocyte count <0.1x109/L Active immunosuppressive therapy except for prednisone 10 mg/day (or equivalent) Any other concomitant neoplasia, unless it has been in complete remission for 3 years or longer, except for non-melanoma skin cancer or completely resected in situ carcinoma. Active infection requiring treatment. Active HIV, HBV, or HCV infection. Uncontrolled medical illness.

Calendar

(Last Update: 27/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
10/03/2025	30/04/2025	01/07/2025	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

Fundacio De Recerca Clinic Barcelona-Institut D¿Investigacions Biomediques August Pi I Sunyer Spain

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (30/04/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (30/07/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (01/09/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (19/05/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (26/05/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

Cesnicabtagene autoleucel
DISPERSION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A

Experimental

FLUDARABINE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A

Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL

-
Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A

Experimental

PARACETAMOL
TABLET
ORAL

-
Active Principles: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L04AC07 - TOCILIZUMAB
Active Principles: N/A

Experimental

-
-
ORAL

ATC code: R06A - ANTIHISTAMINICOS PARA USO SISTEMICO
Active Principles: N/A

Experimental

No results