Clinical Trial Using Humanized CART Directed Against BCMA (ARI0002h) in Patients With Relapsed/Refractory Multiple Myeloma to Proteasome Inhibitors, Immunomodulators and Anti-CD38 Antibody

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	30
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico nacional	seguridad, eficacia	Terapia génica

Información

Identificador
2024-515650-24-00 (CTIS)

Cod. Protocolo
CARTBCMA-HCB-01

Transicionado 2019-001472-11

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

Enfermedad investigada
Multiple Myeloma

Título Científico
Pilot study of the infusion of differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-BCMA (TNFRSF17) specificity humanized conjugated with

the co-stimulatory region 4-1BB and signal-transduction CD3z (ARI0002h) in patients with relapsed/refractory multiple myeloma with previous treatment with proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody.

Justificación

No aportado

Objetivo Principal

To assess the safety and efficacy of CARTBCMA ARI0002h in patients with relapsed/refractory multiple myeloma who have received treatment with proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody

Variables de Evaluación Primaria

Primary Efficacy Variable: Overall Response Rate (ORR) in the first 3 months after the first infusion (at least a partial response according to the criteria of the International Myeloma Working Group)
Primary Safety Variable: Rate of patients developing cytokine release syndrome and/or neurological toxicity within 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

To evaluate the effectiveness of ARI0002h
To assess the duration of the response after the administration of ARI0002h
To evaluate the overall survival after the administration of ARI0002h
To evaluate the persistence of ARI0002h cells in peripheral blood after administration
To assess the effect of ARI0002h treatment on the quality of life of patients
To evaluate the adverse events occurring at 3 months and at one year

Variables de Evaluación Secundaria

Duration of the response (see criteria for second dose of ARI0002h -section 6- study treatment)
Response rate over the first year
Complete response rate (CR) at 3 and 6 months after the first infusion
Overall response rate (ORR) at 6 months after the first infusion
Time to complete response
Negative MRD rate in bone marrow at 3 and 6 months
Response rate of extramedullary disease by PET-TC at 3 months

Progression free survival (PFS), defined as the time elapsed between the administration of ARI0002h and the progression of the disease 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 infusion, defined as the time elapsed between the administration of ARI0002h and the progression of the disease or death. Patients who are alive and in complete remission at 12 months will be censored at the time of the last follow-up.
Overall survival (OS) defined as the time elapsed between the infusion of ARI0002h and the death of the patient from any cause. Live patients will be censored at the time of the last follow-up.
Presence of infusion reactions defined as the appearance of any of the following symptoms after administration of intravenous CARTBCMA: cardiac events, chills, dyspnea, fatigue, sudden hypertension, hypotension, nausea, pain, fever, skin rash and urticaria.
Tumor lysis syndrome at any time after the administration of the treatment.
Cytokine release syndrome, according to the criteria and grades defined in the international consensus (Lee, Santomasso et al., 2019).
Neurological toxicity.
Presence of prolonged cytopenia, defined as the reduction of neutrophil or platelet peripheral blood counts, grade 3 or 4 for more than 4 weeks after infusion
Persistence of CART BCMA ARI0002 in peripheral blood, which will be determined by flow cytometry and quantitative PCR of the transgene with monthly periodicity in the first 6 months and subsequently quarterly until 2 years after infusion
Expression of BCMA at diagnosis and in relapse in included patients, evaluated by multiparameter flow cytometry in bone marrow aspirate samples.
Levels of soluble BCMA in serum pre-treatment and during treatment and its correlation with the degree of response of multiple myeloma.
Quality of life: baseline, monthly for the first 6 months, and then quarterly until 2 years after the infusion
Time to better response

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients between the age of 18 and 75 years with diagnosis of multiple myeloma.
Disease measurable by monoclonal component in serum and/or urine or by free light chains in serum according to the eligibility criteria for clinical trials of the International Myeloma Working Group
Previous two or more lines of treatment. Patients must have received at least a proteasome inhibitor (such as bortezomib or carfilzomib), an immunomodulatory drug (lenalidomide or pomalidomide) and an anti-CD38 monoclonal antibody (such as daratumumab)
Refractory to the last line of treatment
ECOG functional status ranging from 0 to 2
Life expectancy over 3 months
Patients who, after being informed, give their consent by signing the Informed Consent document

Criterios de Exclusión

Previous allogeneic transplant in the prior 6 months to inclusion or GVHD that requires active systemic immunosuppressive treatment. Women of childbearing age, including those whose last menstrual cycle was in the year prior to screening, who cannot or do not wish to use highly effective contraceptive methods from the beginning

until the end of the study. Men who cannot or do not wish to use highly effective contraceptive methods from the beginning to the end of the study. Contraindication to receive conditioning chemotherapy Absolute lymphocyte count <0.1x109 / L Previous neoplasia, except if patients have been in complete remission > 3 years, except for cutaneous carcinoma (non-melanoma) Active infection that requires treatment Active infection by HIV, HBV or HCV Uncontrolled medical disease Severe organic condition that meets any of the following criteria: EF <40%, DLCO <40%, EGFR <50 ml / min, bilirubin> 3 times normal value (except Gilbert syndrome) Previous diagnosis of symptomatic AL amyloidosis Pregnant or lactating women. Women of childbearing age should have a negative pregnancy test in the screening phase

Calendario

(Última actualización: 19/02/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/01/2020	27/05/2020	02/06/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
26/07/2024	No aportado	No aportado	07/11/2025	No aportado

Promotor

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

Tipo de promotor: Comercial

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Centros

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Activo (03/07/2020)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Activo (27/05/2020)

HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Activo (15/06/2020)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Activo (14/07/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Activo (13/07/2020)

Medicamentos

Cesnicabtagene autoleucel
DISPERSION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

CYCLOPHOSPHAMIDE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

FLUDARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS ADMINISTRATION

-

Principios Activos: N/A

Experimental

TOCILIZUMAB
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Experimental

PARACETAMOL
TABLET
ORAL AND IV

-

Principios Activos: N/A

Experimental

ALLOPURINOL
TABLET
ORAL

-

Principios Activos: N/A

Experimental

DEXCHLORPHENIRAMINE
TABLET
ORAL AND IV

-

Principios Activos: N/A

Experimental

Sin resultados

Clinical Trial Using Humanized CART Directed Against BCMA (ARI0002h) in Patients With Relapsed/Refractory Multiple Myeloma to Proteasome Inhibitors, Immunomodulators and Anti-CD38 Antibody

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	30
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National multicenter	safety, effectiveness	Gene therapy

Information

Identifier
2024-515650-24-00 (CTIS)

Protocol Code
CARTBCMA-HCB-01

Transitioned 2019-001472-11

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

Investigated Disease
Multiple Myeloma

Scientific Title
Pilot study of the infusion of differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-BCMA (TNFRSF17) specificity humanized conjugated with

the co-stimulatory region 4-1BB and signal-transduction CD3z (ARI0002h) in patients with relapsed/refractory multiple myeloma with previous treatment with proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody.

Rationale

Not provided

Main Objective

To assess the safety and efficacy of CARTBCMA ARI0002h in patients with relapsed/refractory multiple myeloma who have received treatment with proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody

Primary Endpoints

Primary Efficacy Variable: Overall Response Rate (ORR) in the first 3 months after the first infusion (at least a partial response according to the criteria of the International Myeloma Working Group)
Primary Safety Variable: Rate of patients developing cytokine release syndrome and/or neurological toxicity within 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

To evaluate the effectiveness of ARI0002h
To assess the duration of the response after the administration of ARI0002h
To evaluate the overall survival after the administration of ARI0002h
To evaluate the persistence of ARI0002h cells in peripheral blood after administration
To assess the effect of ARI0002h treatment on the quality of life of patients
To evaluate the adverse events occurring at 3 months and at one year

Secondary Endpoints

Duration of the response (see criteria for second dose of ARI0002h -section 6- study treatment)
Response rate over the first year
Complete response rate (CR) at 3 and 6 months after the first infusion
Overall response rate (ORR) at 6 months after the first infusion
Time to complete response
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Quality of life: baseline, monthly for the first 6 months, and then quarterly until 2 years after the infusion
Time to better response

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Exclusion criteria

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Calendar

(Last Update: 19/02/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/01/2020	27/05/2020	02/06/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
26/07/2024	Not aported	Not aported	07/11/2025	Not aported

Sponsor

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

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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Pamplona/Iruña

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Active (27/05/2020)

HOSPITAL CLÍNIC DE BARCELONA

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Active (15/06/2020)

HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Active (14/07/2020)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Active (13/07/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Medication

Cesnicabtagene autoleucel
DISPERSION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

FLUDARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS ADMINISTRATION

-

Active Principles: N/A

Experimental

TOCILIZUMAB
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

-

Active Principles: N/A

Experimental

PARACETAMOL
TABLET
ORAL AND IV

-

Active Principles: N/A

Experimental

ALLOPURINOL
TABLET
ORAL

-

Active Principles: N/A

Experimental

DEXCHLORPHENIRAMINE
TABLET
ORAL AND IV

-

Active Principles: N/A

Experimental

No results