A study with three treatments for higher-risk chronic myelomonocytic leukaemia.

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	10
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento	NO

Información

Identificador
2024-511102-22-00 (CTIS)

Cod. Protocolo
PATROL

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
chronic myelomonocytic Leukemia

Título Científico
Phase II study of standard of care therapy azacitidine (AZA) combined with venetoclax (VEN) and Tagraxofusp (TAG) in patients with higher-Risk chronic myelomonocytic Leukemia (CMML): the PATROL Study

Justificación

No aportado

Objetivo Principal

Main objective is the primary objective of the trial is to generate data on the efficacy by CR, mCR, or PR of the combination of the SOC agent AZA combined with venetoclax (VEN) and tagraxofusp (TAG) in the studied patient population in a descriptive manner and by statistical analysis.

Variables de Evaluación Primaria

The primary outcome measure is the response rate defined as CR or mCR or PR after 3 cycles of treatment. Response will be assessed according to Savona et al., 20151.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Tolerability and safety of the combination
Evaluate the efficacy in terms of Overall survival (OS), time to leukemia transformation (TLT), median duration of response until EOT
Evaluate the efficacy in terms of Hematologic improvement after 3 cycles of treatment (IWG 2018/2023 criteria)
Evaluate the efficacy in terms of Transfusion independence after 3 cycles of treatment (IWG 2018/2023 criteria)
Quality of life

Variables de Evaluación Secundaria

Adverse events (AEs) and serious adverse events (SAEs), clinical laboratory values, vital signs, ECG, and ECHO/MUGA parameters
Overall survival (OS), time to leukemia transformation (TLT), median duration of response until EOT
Proportion of patients achieving hematologic improvement after 3 cycles of treatment (IWG 2018/2023 criteria)
Proportion of patients achieving transfusion independence after 3 cycles of treatment (IWG 2018/2023 criteria)
Change of quality of life after 3 cycles and 12 cycles of treatment compared to baseline

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Signed written informed consent 10. Women of childbearing potential and practicing a highly effective method of birth control according to the Clinical Trial Facilitation Coordination Group Recommendation (Version 1.1, 2020)3: combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation: o oral o intravaginal o transdermal progestogen-only hormonal contraception associated with inhibition of ovulation: o oral o injectable o implantable intrauterine device (IUD) intrauterine hormone-releasing system (IUS) bilateral tubal occlusion vasectomised partner sexual abstinence For females, these requirements apply during the treatment period and for 6 months after the end of dosing. 11. A woman of childbearing potential must have a negative serum (-human chorionic gonadotropin [-hCG]) pregnancy test within one week of treatment initiation and agree to be tested (serum or urine) on day 1 of every cycle and at EOT 12. A man who is sexually active with a woman of childbearing potential and has not had a vasectomy must agree to use a highly effective method of contraception) and all men must also not donate sperm. Highly effective methods of contraception include double-barrier contraception, total abstinence, vasectomization with confirmed azoospermia, female partner with an intrauterine device, etc.). For males, these requirements apply during the study treatment period and for 3 months after the end of dosing. 2. Male and female 18 years at date of signing informed consent 3. Must be able to adhere to the study visit schedule and other protocol requirements 4. CMML diagnosis according to WHO 2022 criteria 5. CPSS risk intermediate-2 or high2 (HR) CMML at study entry (WBC prior to HY used to compute CPSS at inclusion in HY-exposed patients, see below) 6. Patients who are eligible for and will receive azacitidine (AZA) as per standard of care. 7. Performance status 0-2 on the Eastern Cooperative Oncology Group (ECOG) Scale 8. Adequate organ function including the following: Liver: o Total bilirubin < 1.5 times upper limit of normal (ULN) (except moderate unconjugated hyperbilirubinemia due to intra medullary hemolysis or due to Gilbert syndrome), AND o Alanine transaminase (ALT) and aspartate transaminase (AST) < 2.5 times ULN Renal: Creatinine clearance >/= 45 mL/minute Cardiac o Left ventricular ejection fraction (LVEF) 50% by multigated acquisition scan (MUGA) or 2-dimensional (2-D) echocardiogram (ECHO) within 28 days prior to the start of therapy o No clinically significant abnormalities on a 12-lead electrocardiogram (ECG) Albumin: Serum albumin 3.2 g/dL (note: albumin infusions are not permitted in order to enable eligibility) 9. Availability of blood counts and transfusion events for previous 8 weeks

Criterios de Exclusión

1. CMML with t (5 ;12) or PDGFRB rearrangement that may be treated with imatinib 10. Serious concomitant systemic disorder, including active bacterial, fungal, psychiatric illness, or viral infection that in the opinion of the investigator, would compromise the safety of the patient and/or his/her ability to complete the study. 11. Medical condition requiring therapies with CYP3A inducing activity. All CYP3A inducers should be discontinued 7 days prior to the first dose of study drug 12. Patients with known CNS involvement 13. Females who are pregnant or are currently breastfeeding or planning to become pregnant while enrolled in this study or within 6 months after the end of dosing 14. Patient is a man who plans to father a child while enrolled in this study or within 3 months after the end of dosing 15. The patient is receiving immunosuppressive therapy for any reason, with the exception of low-dose prednisone (10 mg/day) or equivalent 16. The patient has persistent clinically significant toxicities Grade 2 from previous therapies, including cytotoxic chemotherapy, targeted therapies, biological therapies, or immunotherapies, not readily controlled by supportive measures (excluding alopecia, nausea, and fatigue) 17. The patient has clinically significant cardiovascular disease (e.g. uncontrolled or any New York Heart Association Class 3 or 4 congestive heart failure, uncontrolled angina, history of myocardial infarction, unstable angina or stroke within 6 months prior to study entry, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication). 18. The patient has uncontrolled, clinically significant pulmonary disease (e.g. chronic obstructive pulmonary disease, pulmonary hypertension) that in the opinion of the Investigator would put the patient at significant risk for pulmonary complications during the study. 19. The patient has known positive status for human immunodeficiency virus (HIV) or active or chronic Hepatitis B or Hepatitis C. 2. Myeloproliferative / myelodysplastic neoplasm other than CMML 20. Patient is unable to attend site visits as patient is in custody by order of an authority or a court of law 21. Participation in another interventional clinical study within the last 3 months prior to signing the ICF or simultaneous participation in other clinical studies 22. Previous assignment to treatment during this study 23. Close affiliation with the investigator (e.g. a close relative) or persons working at the study site 24. Patient is an employee of the sponsor or involved CRO 25. Criteria which in the opinion of the investigator preclude participation for scientific reasons, for

reasons of compliance, or for reasons of the patients safety 3. Bone marrow or peripheral blood blasts (including promonocytes) 20% 4. Patients with unavailable CPSS at inclusion (WBC prior to HY used to compute CPSS at inclusion in HY-exposed patients) or with a CPSS low or intermediate-1 at study entry 5. Patient has received an experimental or investigational drug or used an invasive investigational medical device within 14 days prior to day 1 of C1 6. Prior treatment with TAG, VEN and/or HMA treatment, including AZA/CC-486, decitabine (DEC), SGI-110, AST7227. Prior treatment with Erythropoiesis Stimulating Agents (ESA) or hydroxyurea (HY) is acceptable, with a > 15 days washout from ESAs and > 3 days washout from HY 7. Patients who previously received an allogeneic stem cell transplantation (HSCT) for CMML or an antecedent hematological malignancy. Those never transplanted but eligible for HSCT are eligible for the trial. 8. Major surgery within 4 weeks prior to day 1 of C1 (excluding the placement of vascular access and other minor surgical procedures) 9. Prior malignancy (except in situ cervix carcinoma, limited basal cell carcinoma, asymptomatic prostatic cancer not requiring treatment, or other tumors if not active during the last 2 years)

Calendario

(Última actualización: 18/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
07/03/2025	18/06/2025	30/03/2026	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

GCP-Service International West GmbH Germany

Siegfeldstrasse 11

Contact Person

sponsor representativ

+494218967661

germany@gcp-service.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIM Área de Salud de Salamanca

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comite.etico.husa@saludcastillayleon.es

923291100

Centros

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology Services

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

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematologia

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology Service

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

Institut Catala D´oncologia

Badalona

BARCELONA

Institut Català d' Oncologia

Medicamentos

Venetoclax
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

ELZONRIS 1 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XX67 - TAGRAXOFUSP
Principios Activos: N/A

Experimental

Sin resultados

A study with three treatments for higher-risk chronic myelomonocytic leukaemia.

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	10
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment	NO

Information

Identifier
2024-511102-22-00 (CTIS)

Protocol Code
PATROL

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
chronic myelomonocytic Leukemia

Scientific Title
Phase II study of standard of care therapy azacitidine (AZA) combined with venetoclax (VEN) and Tagraxofusp (TAG) in patients with higher-Risk chronic myelomonocytic Leukemia (CMML): the PATROL Study

Rationale

Not provided

Main Objective

Main objective is the primary objective of the trial is to generate data on the efficacy by CR, mCR, or PR of the combination of the SOC agent AZA combined with venetoclax (VEN) and tagraxofusp (TAG) in the studied patient population in a descriptive manner and by statistical analysis.

Primary Endpoints

The primary outcome measure is the response rate defined as CR or mCR or PR after 3 cycles of treatment.
Response will be assessed according to Savona et al., 20151.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Tolerability and safety of the combination
Evaluate the efficacy in terms of Overall survival (OS), time to leukemia transformation (TLT), median duration of response until EOT
Evaluate the efficacy in terms of Hematologic improvement after 3 cycles of treatment (IWG 2018/2023 criteria)
Evaluate the efficacy in terms of Transfusion independence after 3 cycles of treatment (IWG 2018/2023 criteria)
Quality of life

Secondary Endpoints

Adverse events (AEs) and serious adverse events (SAEs), clinical laboratory values, vital signs, ECG, and ECHO/MUGA parameters
Overall survival (OS), time to leukemia transformation (TLT), median duration of response until EOT
Proportion of patients achieving hematologic improvement after 3 cycles of treatment (IWG 2018/2023 criteria)
Proportion of patients achieving transfusion independence after 3 cycles of treatment (IWG 2018/2023 criteria)
Change of quality of life after 3 cycles and 12 cycles of treatment compared to baseline

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Signed written informed consent 10. Women of childbearing potential and practicing a highly effective method of birth control according to the Clinical Trial Facilitation Coordination Group Recommendation (Version 1.1, 2020)3: combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation: o oral o intravaginal o transdermal progestogen-only hormonal contraception associated with inhibition of ovulation: o oral o injectable o implantable intrauterine device (IUD) intrauterine hormone-releasing system (IUS) bilateral tubal occlusion vasectomised partner sexual abstinence For females, these requirements apply during the treatment period and for 6 months after the end of dosing. 11. A woman of childbearing potential must have a negative serum (-human chorionic gonadotropin [-hCG]) pregnancy test within one week of treatment initiation and agree to be tested (serum or urine) on day 1 of every cycle and at EOT 12. A man who is sexually active with a woman of childbearing potential and has not had a vasectomy must agree to use a highly effective method of contraception) and all men must also not donate sperm. Highly effective methods of contraception include double-barrier contraception, total abstinence, vasectomization with confirmed azoospermia, female partner with an intrauterine device, etc.). For males, these requirements apply during the study treatment period and for 3 months after the end of dosing. 2. Male and female 18 years at date of signing informed consent 3. Must be able to adhere to the study visit schedule and other protocol requirements 4. CMML diagnosis according to WHO 2022 criteria 5. CPSS risk intermediate-2 or high2 (HR) CMML at study entry (WBC prior to HY used to compute CPSS at inclusion in HY-exposed patients, see below) 6. Patients who are eligible for and will receive azacitidine (AZA) as per standard of care. 7. Performance status 0-2 on the Eastern Cooperative Oncology Group (ECOG) Scale 8. Adequate organ function including the following: Liver: o Total bilirubin < 1.5 times upper limit of normal (ULN) (except moderate unconjugated hyperbilirubinemia due to intra medullary hemolysis or due to Gilbert syndrome), AND o Alanine transaminase (ALT) and aspartate transaminase (AST) < 2.5 times ULN Renal: Creatinine clearance >/= 45 mL/minute Cardiac o Left ventricular ejection fraction (LVEF) 50% by multigated acquisition scan (MUGA) or 2-dimensional (2-D) echocardiogram (ECHO) within 28 days prior to the start of therapy o No clinically significant abnormalities on a 12-lead electrocardiogram (ECG) Albumin: Serum albumin 3.2 g/dL (note: albumin infusions are not permitted in order to enable eligibility) 9. Availability of blood counts and transfusion events for previous 8 weeks

Exclusion criteria

1. CMML with t (5 ;12) or PDGFRB rearrangement that may be treated with imatinib 10. Serious concomitant systemic disorder, including active bacterial, fungal, psychiatric illness, or viral infection that in the opinion of the investigator, would compromise the safety of the patient and/or his/her ability to complete the study. 11. Medical condition requiring therapies with CYP3A inducing activity. All CYP3A inducers should be discontinued 7 days prior to the first dose of study drug 12. Patients with known CNS involvement 13. Females who are pregnant or are currently breastfeeding or planning to become pregnant while enrolled in this study or within 6 months after the end of dosing 14. Patient is a man who plans to father a child while enrolled in this study or within 3 months after the end of dosing 15. The patient is receiving immunosuppressive therapy for any reason, with the exception of low-dose prednisone (10 mg/day) or equivalent 16. The patient has persistent clinically significant toxicities Grade 2 from previous therapies, including cytotoxic chemotherapy, targeted therapies, biological therapies, or immunotherapies, not readily controlled by supportive measures (excluding alopecia, nausea, and fatigue) 17. The patient has clinically significant cardiovascular disease (e.g. uncontrolled or any New York Heart Association Class 3 or 4 congestive heart failure, uncontrolled angina, history of myocardial infarction, unstable angina or stroke within 6 months prior to study entry, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication). 18. The patient has uncontrolled, clinically significant pulmonary disease (e.g. chronic obstructive pulmonary disease, pulmonary hypertension) that in the opinion of the Investigator would put the patient at significant risk for pulmonary complications during the study. 19. The patient has known positive status for human immunodeficiency virus (HIV) or active or chronic Hepatitis B or Hepatitis C. 2. Myeloproliferative / myelodysplastic neoplasm other than CMML 20. Patient is unable to attend site visits as patient is in custody by order of an authority or a court of law 21. Participation in another interventional clinical study within the last 3 months prior to signing the ICF or simultaneous participation in other clinical studies 22. Previous assignment to treatment during this study 23. Close affiliation with the investigator (e.g. a close relative) or persons working at the study site 24. Patient is an employee of the sponsor or involved CRO 25. Criteria which in the opinion of the investigator preclude participation for scientific reasons, for

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Calendar

(Last Update: 18/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
07/03/2025	18/06/2025	30/03/2026	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

GCP-Service International West GmbH Germany

Siegfeldstrasse 11

Contact Person

sponsor representativ

+494218967661

germany@gcp-service.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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923291100

Sites

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology Services

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

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematologia

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology Service

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

Institut Catala D´oncologia

Badalona

BARCELONA

Institut Català d' Oncologia

Medication

Venetoclax
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

ELZONRIS 1 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XX67 - TAGRAXOFUSP

Active Principles: N/A

Experimental

No results