IMPACT-AML: A RANDOMIZED PRAGMATIC CLINICAL TRIAL FOR RELAPSE OR REFRACTORY ACUTE MYELOID LEUKEMIA

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	15
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	Si	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento	NO

Información

Identificador
2024-514517-35-00 (CTIS)

Cod. Protocolo
IRST204.07

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

Enfermedad investigada
Acute myeloid leukemia

Título Científico
IMPACT-AML: A RANDOMIZED PRAGMATIC CLINICAL TRIAL FOR RELAPSE OR REFRACTORY ACUTE MYELOID LEUKEMIA

Justificación

No aportado

Objetivo Principal

To determine in R/R AML patients the clinical benefit of low intensity therapy as shown by event-free survival compared to high intensity therapy

Variables de Evaluación Primaria

Event-free survival is defined as time from randomization to treatment failure, hematologic relapse from CR/CRh/Cri or death from any cause, whichever occurs first

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To determine if low intensity therapy improves overall survival
To determine if low intensity therapy improves the overall response (CR/CRh/CRi, Morphologic leukemia-free state MLFS)
To determine if low intensity therapy improves patients-reported quality of life
To evaluate the safety of low intensity therapies as compared to high intensity therapies

Variables de Evaluación Secundaria

Overall survival, defined as time from randomization to the date of death from any cause
Overall response rate (CR/CRh/CRi, MLFS) as the best assessment of response during the study treatment and the overall study cohort
Change in Hematologic MalignancyPatient-Reported Outcome (HM-PRO) A-total as defined by the HM-PRO questionnaire between screening and end of treatment assessment.
Proportion of patients experiencing adverse events

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Non-APL AML defined according WHO 2022 (or ICC 2022) criteria 1st or 2nd relapse or refractory according to ELN 2022 Patient is clinically candidate both to low intensity therapy and to high dose chemotherapy in the opinion of the physician Both low intensity therapy and high dose chemotherapy to which patient is candidate are available and can be provided as per local practice No specific treatment protocol can be rationally considered better suited to patient needs. This specifically include, but is not limited to i) the availability of a drug that is already demonstrated superior to comparator arm and can be considered the only standard of care ii) specific contraindications related to fitness or any medical conditions that deem to avoid one of the two arms of this randomization iii) patient willingness to avoid one of the two arm of this randomization iv) lack of social support that make unfeasible one of the two arm of this randomization Male or Female, aged>18 years ECOG performance status <4 A female participant is eligible to participate if she is not pregnant and not breastfeeding. If Women of childbearing potential (WOCBP), negative serum pregnancy test within 14 days of starting treatment must be obtained. WOCBP must adopt highly effective birth control methods, according to guideline Recommendation related to contraception and pregnancy testing in clinical trials. Male patient and his female partner who is of childbearing potential must use 2 methods of birth control (a condom as a barrier method of contraception and one of the highly effective birth control methods, according to guideline Recommendation related to contraception and pregnancy testing in clinical trials. Use of- and compliance to- birth control methods are required beginning at the screening visit and continuing until 6 months following last treatment with study drug. Participant is willing and able to give informed consent for participation in the study

Criterios de Exclusión

Known contraindication to the study drug that will be selected by the treating physician within the list of high or low intensity treatment, according to most update version of SmPC (e.g. hypersensitivity, allergy, organ failure precluding treatment)
Participation in another clinical trial with any investigational agents within 14 days or 5 drug half-lives (whatever comes first) prior to randomization.
Active infections or other clinical conditions that in the opinion of the investigator make the patient ineligible to receive study treatment.

Calendario

(Última actualización: 04/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
02/12/2024	04/03/2025	10/03/2025	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

Istituto Romagnolo Per Lo Studio Dei Tumori Dino Amadori IRST S.r.l. Italy

Via Piero Maroncelli 40

Contact Person

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Monetary support: N/A

Tipo de promotor: No comercial

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923291100

Centros

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

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Activo (31/07/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematology

Activo (31/07/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (04/03/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Medicamentos

[redacted]
-
-
ORAL

Código ATC: L01XJ03 - GLASDEGIB
Principios Activos: N/A
Huérfano **Experimental**

[redacted]
-
-
INTRAVENOUS INFUSION

Código ATC: L01DB06 - IDARUBICINA
Principios Activos: N/A
Experimental

[redacted]
-
-
INTRAVENIOUS INFUSION

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

[redacted]
-
-
INJECTION

Código ATC: L01BC01 - CITARABINA
Principios Activos: N/A
Experimental

[redacted]
-
-
INTRAVENIOUS INFUSION

Código ATC: L01DB02 - DAUNORUBICINA
Principios Activos: N/A
Experimental

[redacted]
-
-
INJECTION

Código ATC: L01BC01 - CITARABINA
Principios Activos: N/A
Experimental

[redacted]
-
-
INJECTION

Código ATC: L01BB04 - CLADRIBINA
Principios Activos: N/A
Experimental

[redacted]
-
-
INTRAVENOUS INFUSION

Código ATC: L01DB07 - MITOXANTRONA
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS INFUSION

Código ATC: L01BB05 - FLUDARABINA
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: L01XX62 - IVOSIDENIB
Principios Activos: N/A

Huérfano Experimental

-
-
INTRAVENOUS INFUSION

Código ATC: L01XX01 - AMSACRINA
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

Código ATC: L01BC07 - AZACITIDINA
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS INFUSION

Código ATC: L01FX02 - GEMTUZUMAB OZOGAMICINA
Principios Activos: N/A

Huérfano Experimental

-
-
INTRAVENOUS

Código ATC: L01BC08 - DECITABINA
Principios Activos: N/A

Huérfano Experimental

-
-
ORAL

-
-
ORAL

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Código ATC: L01XE54 - GILTERITINIB
Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

IMPACT-AML: A RANDOMIZED PRAGMATIC CLINICAL TRIAL FOR RELAPSE OR REFRACTORY ACUTE MYELOID LEUKEMIA

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	15
Results	**Low level of intervention**	**Rare disease**
No results	Yes	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment	NO

Information

Identifier
2024-514517-35-00 (CTIS)

Protocol Code
IRST204.07

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

Investigated Disease
Acute myeloid leukemia

Scientific Title
IMPACT-AML: A RANDOMIZED PRAGMATIC CLINICAL TRIAL FOR RELAPSE OR REFRACTORY ACUTE MYELOID LEUKEMIA

Rationale

Not provided

Main Objective

To determine in R/R AML patients the clinical benefit of low intensity therapy as shown by event-free survival compared to high intensity therapy

Primary Endpoints

Event-free survival is defined as time from randomization to treatment failure, hematologic relapse from CR/CRh/Cri or death from any cause, whichever occurs first

Temporary moments of secondary assessment

Not provided

Secondary Objective

To determine if low intensity therapy improves overall survival
To determine if low intensity therapy improves the overall response (CR/CRh/CRi, Morphologic leukemia-free state MLFS)
To determine if low intensity therapy improves patients-reported quality of life
To evaluate the safety of low intensity therapies as compared to high intensity therapies

Secondary Endpoints

Overall survival, defined as time from randomization to the date of death from any cause
Overall response rate (CR/CRh/CRi, MLFS) as the best assessment of response during the study treatment and the overall study cohort
Change in Hematologic MalignancyPatient-Reported Outcome (HM-PRO) A-total as defined by the HM-PRO questionnaire between screening and end of treatment assessment.
Proportion of patients experiencing adverse events

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Non-APL AML defined according WHO 2022 (or ICC 2022) criteria 1st or 2nd relapse or refractory according to ELN 2022 Patient is clinically candidate both to low intensity therapy and to high dose chemotherapy in the opinion of the physician Both low intensity therapy and high dose chemotherapy to which patient is candidate are available and can be provided as per local practice No specific treatment protocol can be rationally considered better suited to patient needs. This specifically include, but is not limited to i) the availability of a drug that is already demonstrated superior to comparator arm and can be considered the only standard of care ii) specific contraindications related to fitness or any medical conditions that deem to avoid one of the two arms of this randomization iii) patient willingness to avoid one of the two arm of this randomization iv) lack of social support that make unfeasible one of the two arm of this randomization Male or Female, aged>18 years ECOG performance status <4 A female participant is eligible to participate if she is not pregnant and not breastfeeding. If Women of childbearing potential (WOCBP), negative serum pregnancy test within 14 days of starting treatment must be obtained. WOCBP must adopt highly effective birth control methods, according to guideline Recommendation related to contraception and pregnancy testing in clinical trials. Male patient and his female partner who is of childbearing potential must use 2 methods of birth control (a condom as a barrier method of contraception and one of the highly effective birth control methods, according to guideline Recommendation related to contraception and pregnancy testing in clinical trials. Use of- and compliance to- birth control methods are required beginning at the screening visit and continuing until 6 months following last treatment with study drug. Participant is willing and able to give informed consent for participation in the study

Exclusion criteria

Known contraindication to the study drug that will be selected by the treating physician within the list of high or low intensity treatment, according to most update version of SmPC (e.g. hypersensitivity, allergy, organ failure precluding treatment)
Participation in another clinical trial with any investigational agents within 14 days or 5 drug half-lives (whatever comes first) prior to randomization.
Active infections or other clinical conditions that in the opinion of the investigator make the patient ineligible to receive study treatment.

Calendar

(Last Update: 04/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
02/12/2024	04/03/2025	10/03/2025	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

Istituto Romagnolo Per Lo Studio Dei Tumori Dino Amadori IRST S.r.l. Italy

Via Piero Maroncelli 40

Contact Person

Oriana Nanni

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cc.ubsc@irst.emr.it

Monetary support: N/A

Sponsor type: No commercial

Ceim

CEIM Área de Salud de Salamanca

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comite.etico.husa@saludcastillayleon.es

923291100

Sites

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

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Active (31/07/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematology

Active (31/07/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (04/03/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Medication

[redacted]
-
-
ORAL

ATC code: L01XJ03 - GLASDEGIB
Active Principles: N/A
Orphan Experimental

[redacted]
-
-
INTRAVENOUS INFUSION

ATC code: L01DB06 - IDARUBICINA
Active Principles: N/A
Experimental

[redacted]
-
-
INTRAVENIOUS INFUSION

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

[redacted]
-
-
INJECTION

ATC code: L01BC01 - CITARABINA
Active Principles: N/A
Experimental

[redacted]
-
-
INTRAVENIOUS INFUSION

ATC code: L01DB02 - DAUNORUBICINA
Active Principles: N/A
Experimental

[redacted]
-
-
INJECTION

ATC code: L01BC01 - CITARABINA
Active Principles: N/A
Experimental

[redacted]
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-
INJECTION

ATC code: L01BB04 - CLADRIBINA
Active Principles: N/A
Experimental

[redacted]
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ATC code: L01DB07 - MITOXANTRONA
Active Principles: N/A
Experimental

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-
INTRAVENOUS INFUSION

ATC code: L01BB05 - FLUDARABINA
Active Principles: N/A

Experimental

-
-
ORAL

ATC code: L01XX62 - IVOSIDENIB
Active Principles: N/A

Orphan Experimental

-
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INTRAVENOUS INFUSION

ATC code: L01XX01 - AMSACRINA
Active Principles: N/A

Experimental

-
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INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

ATC code: L01BC07 - AZACITIDINA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS INFUSION

ATC code: L01FX02 - GEMTUZUMAB OZOGAMICINA
Active Principles: N/A

Orphan Experimental

-
-
INTRAVENOUS

ATC code: L01BC08 - DECITABINA
Active Principles: N/A

Orphan Experimental

-
-
ORAL

-
-
ORAL

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A
Experimental

ATC code: L01XE54 - GILTERITINIB
Active Principles: N/A
Orphan **Experimental**

No results