A multicenter randomized trial of fosfomycin versus ciprofloxacin for febrile neutropenia in hematologic patients: efficacy and microbiologic safety.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	156
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	Si	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	profilaxis	NO

Información

Identificador
2024-520336-14-00 (CTIS)

Cod. Protocolo
FOVOCIP

Transicionado 2021-000354-25

Área terapéutica
·Not possible to specify
·Enfermedades [C] - Hematología [C15]

Enfermedad investigada
Post-chemotherapy neutropenia with high risk of developing infection in patients with acute leukemia undergoing induction, autologous or allogeneic hematopoietic stem cell transplantation (HSCT).

Título Científico
A multicenter randomized trial of fosfomycin versus ciprofloxacin for febrile neutropenia in hematologic patients: efficacy and microbiologic safety.

Justificación

No aportado

Objetivo Principal

To demonstrate non-inferiority in efficacy of oral fosfomycin versus oral ciprofloxacin in preventing febrile neutropenia in patients with acute leukemia treated with intensive chemotherapy and/or recipients of hematopoietic stem cell transplantation hematopoietic stem cell transplantation.

Variables de Evaluación Primaria

febrile neutropenia requiring antibacterial treatment Absolute Neutrophil Count (ANR) >0.5x109/L If the subject fails to achieve more than 0.5x109/L neutrophils the study will end when more than 60 days have elapsed since the onset of neutropenia, or on the first day of the next chemotherapy cycle (whichever is earlier) death

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Febrile neutropenia of infectious etiology
Compare overall survival from baseline to resolution of neutropenia in both treatment arms
To evaluate the safety and tolerability of both prophylactic strategies.
Perform surveillance cultures to determine the rate of Gram-negative multiresistant colonization (GNMRB), analyze the time course of colonization, and identify clinical factors associated with the clearance or persistence of GNMRB bacteria in the gut of previously colonized patients.
To evaluate the utility of a metagenomic approach in the identification of underdetected colonization, as compared to traditional surveillance cultures.
To analyze changes in the fecal microbiome of patients from initiation of chemotherapy to resolution of neutropenia and compare these changes between both treatment arms

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subjects must be able to understand the study procedures, comply with them, and give written informed consent prior to any specific study procedure. Adult subjects 18 years of age with a diagnosis of acute leukemia who are to receive their first course of chemotherapy or adult subjects 18 years of age who are candidates for a first stem cell transplant. Expected neutropenia of 100x109/L lasting at least seven days. In the case of an expected range of 100-500x109/L neutropenia lasting seven days or longer, at least one of the following risk factors for infection must be present: b. Expected grade 3-4 mucositis. c. Age 65 years. d. Comorbidity index (HCTI) 3. e. Serum albumin< 35 g/L. f. Total dose of etoposide > 500 mg/m2. g. Total dose of cytarabine > 1 g/m2. h. Active or refractory neoplasia at the time of stem cell transplantation. Performance status (Eastern Cooperative Oncology Group, ECOG) of 0 to 3. Adequate organ function defined as: Adequate organ function defined as: - Liver : bilirubin, alkaline phosphatase or SGOT < 3 times the upper limit of normal (unless attributable to tumor activity). - Renal : creatinine 250 mol/l (2.5 mg/dL) (unless attributable to AML activity). Life expectancy greater than 3 months Women of childbearing age should not be pregnant or breastfeeding and should have a negative pregnancy test at the time of screening. Women of childbearing age and men with female partners of childbearing age must agree to practice 2 highly effective contraceptive measures and must agree not to become pregnant or father a child while receiving any study therapy and for at least 3 months after completion of treatment.

Criterios de Exclusión

Hypersensitivity to fluoroquinolones or fosfomycin.
Treatment with broad-spectrum antimicrobial therapy within 4 weeks of the first study treatment.
Prior intensive chemotherapy or stem cell transplantation. Treatment with hydroxyurea or corticosteroids used to control white blood cell count is allowed
Fever of infectious origin or documented infection within 4 weeks of first study treatment
Presence of any serious psychiatric illness or physical condition that, in the judgment of the physicians, contraindicates the patient's inclusion in the clinical trial.

Calendario

(Última actualización: 21/01/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/11/2021	14/03/2022	No aportado	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

Fundacion Para La Investigacion Y La Innovacion Biosanitaria Del Principado De Asturias Spain

Avenida De Roma Sn

Contact Person

TERESA BERNAL

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Monetary support: N/A

Tipo de promotor: Comercial

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CEIm de Cantabria

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Centros

Activo (01/04/2022)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

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

Hospital Clinico Universitario Lozano Blesa

Zaragoza

ZARAGOZA

hematologia

Activo (25/05/2022)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

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

Hospital San Pedro De Alcantara

Caceres

CÁCERES

hematologia

Activo (14/03/2022)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Activo (08/07/2022)

HOSPITAL UNIVERSITARIO CLINICO SAN CARLOS

Madrid

MADRID

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

Hospital Universitario De Burgos

Burgos

BURGOS

hematologia

Activo (11/07/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Activo (26/04/2022)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Activo (17/05/2022)

HOSPITAL UNIVERSITARIO REGIONAL DE MALAGA

Málaga

MÁLAGA

Activo (30/03/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Medicamentos

-

-

ORAL

Código ATC: J01MA02 - CIPROFLOXACINO

Principios Activos: N/A

Experimental

-

-

ORAL

Código ATC: J01XX01 - FOSFOMICINA

Principios Activos: N/A

Experimental

Sin resultados

A multicenter randomized trial of fosfomycin versus ciprofloxacin for febrile neutropenia in hematologic patients: efficacy and microbiologic safety.

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	156
Results	**Low level of intervention**	**Rare disease**
No results	Yes	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	prophylaxis	NO

Information

Identifier
2024-520336-14-00 (CTIS)

Protocol Code
FOVOCIP

Transitioned 2021-000354-25

Therapeutic area
·Not possible to specify
·Diseases [C] - Hemic and Lymphatic Diseases [C15]

Investigated Disease
Post-chemotherapy neutropenia with high risk of developing infection in patients with acute leukemia undergoing induction, autologous or allogeneic hematopoietic stem cell transplantation (HSCT).

Scientific Title
A multicenter randomized trial of fosfomycin versus ciprofloxacin for febrile neutropenia in hematologic patients: efficacy and microbiologic safety.

Rationale

Not provided

Main Objective

To demonstrate non-inferiority in efficacy of oral fosfomycin versus oral ciprofloxacin in preventing febrile neutropenia in patients with acute leukemia treated with intensive chemotherapy and/or recipients of hematopoietic stem cell transplantation hematopoietic stem cell transplantation.

Primary Endpoints

febrile neutropenia requiring antibacterial treatment Absolute Neutrophil Count (ANR) >0.5x109/L If the subject fails to achieve more than 0.5x109/L neutrophils the study will end when more than 60 days have elapsed since the onset of neutropenia, or on the first day of the next chemotherapy cycle (whichever is earlier) death

Temporary moments of secondary assessment

Not provided

Secondary Objective

Febrile neutropenia of infectious etiology
Compare overall survival from baseline to resolution of neutropenia in both treatment arms
To evaluate the safety and tolerability of both prophylactic strategies.
Perform surveillance cultures to determine the rate of Gram-negative multiresistant colonization (GNMRB), analyze the time course of colonization, and identify clinical factors associated with the clearance or persistence of GNMRB bacteria in the gut of previously colonized patients.
To evaluate the utility of a metagenomic approach in the identification of underdetected colonization, as compared to traditional surveillance cultures.
To analyze changes in the fecal microbiome of patients from initiation of chemotherapy to resolution of neutropenia and compare these changes between both treatment arms

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subjects must be able to understand the study procedures, comply with them, and give written informed consent prior to any specific study procedure. Adult subjects 18 years of age with a diagnosis of acute leukemia who are to receive their first course of chemotherapy or adult subjects 18 years of age who are candidates for a first stem cell transplant. Expected neutropenia of 100x109/L lasting at least seven days. In the case of an expected range of 100-500x109/L neutropenia lasting seven days or longer, at least one of the following risk factors for infection must be present: b. Expected grade 3-4 mucositis. c. Age 65 years. d. Comorbidity index (HCTI) 3. e. Serum albumin< 35 g/L. f. Total dose of etoposide > 500 mg/m2. g. Total dose of cytarabine > 1 g/m2. h. Active or refractory neoplasia at the time of stem cell transplantation. Performance status (Eastern Cooperative Oncology Group, ECOG) of 0 to 3. Adequate organ function defined as: Adequate organ function defined as: - Liver : bilirubin, alkaline phosphatase or SGOT < 3 times the upper limit of normal (unless attributable to tumor activity). - Renal : creatinine 250 mol/l (2.5 mg/dL) (unless attributable to AML activity). Life expectancy greater than 3 months Women of childbearing age should not be pregnant or breastfeeding and should have a negative pregnancy test at the time of screening. Women of childbearing age and men with female partners of childbearing age must agree to practice 2 highly effective contraceptive measures and must agree not to become pregnant or father a child while receiving any study therapy and for at least 3 months after completion of treatment.

Exclusion criteria

Hypersensitivity to fluoroquinolones or fosfomycin.
Treatment with broad-spectrum antimicrobial therapy within 4 weeks of the first study treatment.
Prior intensive chemotherapy or stem cell transplantation. Treatment with hydroxyurea or corticosteroids used to control white blood cell count is allowed
Fever of infectious origin or documented infection within 4 weeks of first study treatment
Presence of any serious psychiatric illness or physical condition that, in the judgment of the physicians, contraindicates the patient's inclusion in the clinical trial.

Calendar

(Last Update: 21/01/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
11/11/2021	14/03/2022	Not aported	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

Fundacion Para La Investigacion Y La Innovacion Biosanitaria Del Principado De Asturias Spain

Avenida De Roma Sn

Contact Person

TERESA BERNAL

618753904

bernalmaria@uniovi.es

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (01/04/2022)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

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

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hematologia

Active (25/05/2022)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

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

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Active (11/07/2022)

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HOSPITAL UNIVERSITARIO LA PAZ

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Active (30/03/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Medication

-

-

ORAL

ATC code: J01MA02 - CIPROFLOXACINO

Active Principles: N/A

Experimental

-

-

ORAL

ATC code: J01XX01 - FOSFOMICINA

Active Principles: N/A

Experimental

No results