Effect of Tofacitinib on coagulation and platelet function, and its role in thromboembolic events

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	60
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad	NO

Información

Identificador
2024-518434-83-01 (CTIS)

Cod. Protocolo
GIS-2021-JAKihemo

Transicionado 2021-002211-65

Área terapéutica
Enfermedades [C] - Patologías digestivas [C06]|

Enfermedad investigada
ulcerative colitis

Título Científico
Effect of Tofacitinib on coagulation and platelet function, and its role in thromboembolic events

Justificación

No aportado

Objetivo Principal

Evaluate the effect of tofacitinib on platelet function and coagulation in patients with ulcerative colitis.

Variables de Evaluación Primaria

Platelet activation status will be assessed ex vivo in platelet-rich plasma (PRP) samples from UC patients (active and quiescent) and healthy controls incubated in the absence or presence of drug (tofacitinib or anti-TNF). Regarding the in vivo study, platelet activation will be analyzed in samples from patients with active UC before and after initiating treatment with tofacitinib or anti-TNF. It will be mesured by rate of platelet agregation

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Evaluate the in vivo effect of tofacitinib on procoagulant status (platelet function and coagulation) in patients with UC over time.
Determine determine if there is a specific effect of tofacitinib on the hemostasis of UC patients treated with this drug compared to biologic drugs for UC.
Create a repository of biological samples (serum, plasma, nucleic acids, RNA, feces and urine) from a cohort of patients with UC (before and after treatment with tofacitinib or an anti-TNF) that will be used in future complementary studies.

Variables de Evaluación Secundaria

Endoscopic activity will be evaluated by the Mayo endoscopic sub-score; endoscopic activity will be considered as 2.
Endoscopic response will be defined as a decrease of 1 point in the Mayo endoscopic sub-score 3 months after starting treatment.
Endoscopic remission will be defined as an endoscopic subscore 1, 3 months after starting treatment.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Over 18 years old. Diagnosis of UC according to the criteria of the European Crohns and Colitis Organisation (ECCO). Have indication of treatment with anti-TNF (infliximab, adalimumab or golimumab) o tofacitinib Be the first received JAK-inhibitor or anti-TNF with a given mechanism of action. Have endoscopic activity of UC within 1 month of starting the treatment (Mayo endoscopic sub-index of 2). women of childbearing age using contraceptive methods with an error rate <1% per year. Examples of contraceptive methods whose error rate is <1% per year are: 1. Intrauterine device (IUD). 2. Bilateral tubal occlusion. 3. Couple with vasectomy. 4. Sexual abstinence.

Criterios de Exclusión

Under 18 years old.
Pregnancy or lactation.
Alcohol or drug abuse.
Ostomy.
Colectomy.
Active infection with hepatitis B, C or HIV virus.
Indication of anti-TNF or JAK-inhibitors treatment for a cause other than UC.
abdominal surgery in the last 6 months
Have previously received a drug with the same mechanism of action (anti-TNF or JAK-inhibitors)
Medical history of thromboembolic events.
Treatment with anticoagulants, antiplatelets or other drugs that alter the coagulation.
Use of combined hormonal contraceptives or hormone replacement therapy.
Hereditary coagulation disorders.
Refusal to give consent for participation in the study.
Immune-mediated disease.
Neoplasm or active infection.

Calendario

(Última actualización: 05/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/08/2021	28/06/2022	01/06/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	11/06/2026	No aportado	No aportado	No aportado

Promotor

Fundacion Para La Investigacion Biomedica Del Hospital Universitario La Princesa Spain

Calle De Diego De Leon 62

Contact Person

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Monetary support: N/A

Tipo de promotor: No comercial

Ceim

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Centros

Activo (17/05/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Gastroenterology Unit

Medicamentos

GOLIMUMAB
SOLUTION FOR INJECTION IN PRE-FILLED PEN
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Experimental

INFLIXIMAB
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Experimental

ADALIMUMAB
SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Experimental

TOFACITINIB
TABLET
ORAL

-

Principios Activos: N/A

Experimental

Sin resultados

Effect of Tofacitinib on coagulation and platelet function, and its role in thromboembolic events

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase IV	60
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety	NO

Information

Identifier
2024-518434-83-01 (CTIS)

Protocol Code
GIS-2021-JAKihemo

Transitioned 2021-002211-65

Therapeutic area
Diseases [C] - Digestive System Diseases [C06]|

Investigated Disease
ulcerative colitis

Scientific Title
Effect of Tofacitinib on coagulation and platelet function, and its role in thromboembolic events

Rationale

Not provided

Main Objective

Evaluate the effect of tofacitinib on platelet function and coagulation in patients with ulcerative colitis.

Primary Endpoints

Platelet activation status will be assessed ex vivo in platelet-rich plasma (PRP) samples from UC patients (active and quiescent) and healthy controls incubated in the absence or presence of drug (tofacitinib or anti-TNF). Regarding the in vivo study, platelet activation will be analyzed in samples from patients with active UC before and after initiating treatment with tofacitinib or anti-TNF. It will be mesured by rate of platelet agregation

Temporary moments of secondary assessment

Not provided

Secondary Objective

Evaluate the in vivo effect of tofacitinib on procoagulant status (platelet function and coagulation) in patients with UC over time.
Determine determine if there is a specific effect of tofacitinib on the hemostasis of UC patients treated with this drug compared to biologic drugs for UC.
Create a repository of biological samples (serum, plasma, nucleic acids, RNA, feces and urine) from a cohort of patients with UC (before and after treatment with tofacitinib or an anti-TNF) that will be used in future complementary studies.

Secondary Endpoints

Endoscopic activity will be evaluated by the Mayo endoscopic sub-score; endoscopic activity will be considered as 2.
Endoscopic response will be defined as a decrease of 1 point in the Mayo endoscopic sub-score 3 months after starting treatment.
Endoscopic remission will be defined as an endoscopic subscore 1, 3 months after starting treatment.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Over 18 years old. Diagnosis of UC according to the criteria of the European Crohns and Colitis Organisation (ECCO). Have indication of treatment with anti-TNF (infliximab, adalimumab or golimumab) o tofacitinib Be the first received JAK-inhibitor or anti-TNF with a given mechanism of action. Have endoscopic activity of UC within 1 month of starting the treatment (Mayo endoscopic sub-index of 2). women of childbearing age using contraceptive methods with an error rate <1% per year. Examples of contraceptive methods whose error rate is <1% per year are: 1. Intrauterine device (IUD). 2. Bilateral tubal occlusion. 3. Couple with vasectomy. 4. Sexual abstinence.

Exclusion criteria

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Immune-mediated disease.
Neoplasm or active infection.

Calendar

(Last Update: 05/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/08/2021	28/06/2022	01/06/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	11/06/2026	Not aported	Not aported	Not aported

Sponsor

Fundacion Para La Investigacion Biomedica Del Hospital Universitario La Princesa Spain

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Contact Person

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Monetary support: N/A

Sponsor type: No commercial

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Sites

Active (17/05/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Gastroenterology Unit

Medication

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SOLUTION FOR INJECTION IN PRE-FILLED PEN
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

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SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-
Active Principles: N/A
Experimental

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SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

TOFACITINIB
TABLET
ORAL

-
Active Principles: N/A
Experimental

No results