Short-term interruption versus continuous anticoagulation in colorectal polypectomy. A randomized multicenter investigator-initiated non-inferiority clinical trial: the POLYPHEM trial.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	394
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	Si	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-512194-27-01 (CTIS)

Cod. Protocolo
No aportado

Área terapéutica
·Equipos y técnicas terapéuticas, analíticas y diagnósticas [E] - Procedimientos quirúrgicos u operativos [E04]
·Enfermedades [C] - Patologías digestivas [C06]

Enfermedad investigada
Patients receiving oral anticoagulant therapy who are scheduled for elective colonoscopy for any indication.

Título Científico
Short-term interruption versus continuous anticoagulation in colorectal polypectomy. A randomized multicenter investigator-initiated non-inferiority clinical trial: the POLYPHEM trial.

Justificación

No aportado

Objetivo Principal

To evaluate the safety of maintaining anticoagulationtratment during polypectomy in colorrectal lesions.

Variables de Evaluación Primaria

Occurrence of haemorrhage events post-polypectomy

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Explore whether maintaining anticoagulation during polypectomy reduces the risk of thromboembolic events.
Explore if maintaining anticoagulation reduces the carbon footprint (Kg CO2e)

Variables de Evaluación Secundaria

Occurrence of thromboembolic events post-polypectomy
Carbon footprint associated with each intervention arm of the clinical trial

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years or older
Patients undergoing elective outpatient colonoscopy for any indication
Anticoagulant treatment with VKA (acenocoumarol or warfarin) or OACD (dabigatran, edoxaban, apixaban or rivaroxaban) prior to colonoscopy

Criterios de Exclusión

Concomitant antiagregant treatment Planned endoscopic dilatation Severe psychiatric disorder Removal of colorectal lesion by endoscopic submucosal dissection Previous diagnosis of renal failure defined as creatinine >2 mg/dl or clearance < 30 ml/min Planned procedure of high haemorrhagic risk in simultaneously performed gastroscopy Prior trial enrolment. Patients may only be included on one occasion Any clinical situation or concomitant treatment that in the investigator's judgement poses a significant bleeding risk Age > 85 years old Urgent colonoscopy Labile INR (time in therapeutic range less than 60%) documented in the previous 3 months in patients receiving VKAs Supra-therapeutic INR (> 3.5) at the time of the procedure in patients receiving VKA Pregnancy Decompensated liver cirrhosis Inability, in the investigator's judgement, to understand the periprocedural anticoagulation regimen Previously known coagulopathy or bleeding diathesis. Includes plateletopenia < 50,000/µL in the previous 12 months

Calendario

(Última actualización: 23/02/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/06/2024	21/10/2024	21/10/2024	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

Hospital Universitario Ramon Y Cajal Spain

Carretera Del Colmenar Viejo Km 9 100Por El Pardo

Contact Person

Enrique Rodríguez de Santiago

913368000

enrodesan@gmail.com

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Centros

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Gastroenterología

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

Hospital Del Mar

Barcelona

BARCELONA

Servicio de Digestología

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

Hospital San Agustín de Avilés

Avilés (Asturias)

ASTURIAS

Servicio de Gastroenterología y Hepatología

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

Hospital Sierrallana

Torrelavega

CANTABRIA

Servicio de Aparato Digestivo

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Servicio de Gastroenterología y Hepatología

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

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Servicio de Aparato Digestivo

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Servicio de Gastroenterología y Hepatología

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Servicio Gastroenterología y Hepatología

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

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Servicio de Gastroenterología y Hepatología

Medicamentos

-
-
ORAL

Código ATC: B01AE07 - DABIGATRAN ETEXILATO
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: B01AA07 - ACENOCUMAROL
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: B01AF03 - EDOXABAN
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: B01AF01 - B01AF01- RIVAROXABAN
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: B01AA03 - WARFARINA
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: B01AF02 - APIXABAN
Principios Activos: N/A

Experimental

Sin resultados

Short-term interruption versus continuous anticoagulation in colorectal polypectomy. A randomized multicenter investigator-initiated non-inferiority clinical trial: the POLYPHEM trial.

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase IV	394
Results	**Low level of intervention**	**Rare disease**
No results	Yes	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2024-512194-27-01 (CTIS)

Protocol Code
No aportado

Therapeutic area
·Analytical, Diagnostic and Therapeutic Techniques and Equipment [E] - Surgical Procedures, Operative [E04]
·Diseases [C] - Digestive System Diseases [C06]

Investigated Disease
Patients receiving oral anticoagulant therapy who are scheduled for elective colonoscopy for any indication.

Scientific Title
Short-term interruption versus continuous anticoagulation in colorectal polypectomy. A randomized multicenter investigator-initiated non-inferiority clinical trial: the POLYPHEM trial.

Rationale

Not provided

Main Objective

To evaluate the safety of maintaining anticoagulationtratment during polypectomy in colorrectal lesions.

Primary Endpoints

Occurrence of haemorrhage events post-polypectomy

Temporary moments of secondary assessment

Not provided

Secondary Objective

Explore whether maintaining anticoagulation during polypectomy reduces the risk of thromboembolic events.
Explore if maintaining anticoagulation reduces the carbon footprint (Kg CO2e)

Secondary Endpoints

Occurrence of thromboembolic events post-polypectomy
Carbon footprint associated with each intervention arm of the clinical trial

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years or older
Patients undergoing elective outpatient colonoscopy for any indication
Anticoagulant treatment with VKA (acenocoumarol or warfarin) or OACD (dabigatran, edoxaban, apixaban or rivaroxaban) prior to colonoscopy

Exclusion criteria

Concomitant antiagregant treatment Planned endoscopic dilatation Severe psychiatric disorder Removal of colorectal lesion by endoscopic submucosal dissection Previous diagnosis of renal failure defined as creatinine >2 mg/dl or clearance < 30 ml/min Planned procedure of high haemorrhagic risk in simultaneously performed gastroscopy Prior trial enrolment. Patients may only be included on one occasion Any clinical situation or concomitant treatment that in the investigator's judgement poses a significant bleeding risk Age > 85 years old Urgent colonoscopy Labile INR (time in therapeutic range less than 60%) documented in the previous 3 months in patients receiving VKAs Supra-therapeutic INR (> 3.5) at the time of the procedure in patients receiving VKA Pregnancy Decompensated liver cirrhosis Inability, in the investigator's judgement, to understand the periprocedural anticoagulation regimen Previously known coagulopathy or bleeding diathesis. Includes plateletopenia < 50,000/µL in the previous 12 months

Calendar

(Last Update: 23/02/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/06/2024	21/10/2024	21/10/2024	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

Hospital Universitario Ramon Y Cajal Spain

Carretera Del Colmenar Viejo Km 9 100Por El Pardo

Contact Person

Enrique Rodríguez de Santiago

913368000

enrodesan@gmail.com

Monetary support: N/A

Sponsor type: No commercial

Ceim

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917044160

Sites

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Gastroenterología

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

Hospital Del Mar

Barcelona

BARCELONA

Servicio de Digestología

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

Hospital San Agustín de Avilés

Avilés (Asturias)

ASTURIAS

Servicio de Gastroenterología y Hepatología

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

Hospital Sierrallana

Torrelavega

CANTABRIA

Servicio de Aparato Digestivo

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Servicio de Gastroenterología y Hepatología

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

Hospital Universitario De Cabuenes

Gijon

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

Hospital Universitario Puerta De Hierro De Majadahonda

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Servicio Gastroenterología y Hepatología

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

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Servicio de Gastroenterología y Hepatología

Medication

[redacted]
-
-
ORAL

ATC code: B01AE07 - DABIGATRAN ETEXILATO
Active Principles: N/A

Experimental

[redacted]
-
-
ORAL

ATC code: B01AA07 - ACENOCUMAROL
Active Principles: N/A

Experimental

[redacted]
-
-
ORAL

ATC code: B01AF03 - EDOXABAN
Active Principles: N/A

Experimental

[redacted]
-
-
ORAL

ATC code: B01AF01 - B01AF01- RIVAROXABAN
Active Principles: N/A

Experimental

[redacted]
-
-
ORAL

ATC code: B01AA03 - WARFARINA
Active Principles: N/A

Experimental

[redacted]
-
-
ORAL

ATC code: B01AF02 - APIXABAN
Active Principles: N/A

Experimental

No results