

Prophylaxis of venous thromboembolic disease with LMWH (TINzaparin) in patients with metastatic colorectal cancer who start the first line of treatment.

Estado
EC Finalizado

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase III

Participantes esperados
526

Resultados
Sin resultados

Bajo nivel intervención
Si

Enfermedad rara
No

Cobertura geográfica
Multicéntrico nacional

Ámbitos del ensayo
profilaxis

Terapia avanzada
NO

Información

Identificador
2023-508860-31-00 (CTIS)

Cod. Protocolo
GIT-PR0-2022-02

Transicionado 2022-001534-11

Área terapéutica

- Not possible to specify
- Enfermedades [C] - Patologías cardiovasculares [C14]
- Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Stage IV colon or rectal adenocarcinoma (mCRC).

Título Científico

Prophylaxis of venous thromboembolic disease with LMWH (TINzaparin) in patients with metastatic colorectal cancer who start the first line of treatment.

Justificación

No aportado

Objetivo Principal

The main objective of the study is to evaluate the efficacy of 4-months prophylaxis with LMWH (tinzaparin) for the prevention of symptomatic or incidental VTE events in patients with stage IV colorectal cancer (mCRC) that initiate first line systemic treatment (ChT +/- targeted therapy).

Variables de Evaluación Primaria

The primary efficacy endpoint is the cumulative incidence of any VTE event including: Symptomatic non-fatal pulmonary thromboembolism (PE). Symptomatic lower-limb deep vein thromboembolism (sIIDVT). Symptomatic upper extremity deep vein thromboembolism (sueDVT). Incidentally diagnosed PE or proximal DVT. Symptomatic central venous catheter thromboembolism. Incidentally visceral vein thrombosis (iVVT). Symptomatic visceral vein thrombosis (sVVT). VTE-related deaths

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male or female subjects with age 18 years. 2. Written informed consent. 3. Patients with a histologically confirmed diagnosis of stage IV colon or rectal adenocarcinoma (mCRC). 4. Locally assessed BRAF and RAS genomic alterations available during screening. 5. Beginning of the first line of treatment for metastatic disease with chemotherapy +/- targeted therapy (i.e. antiangiogenic, anti-EGFR, encorafenib-cetuximab doublet) or

immunotherapy. 6. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. 7. Life expectancy >6 months.

Criterios de Exclusión

1. Contraindication to tinzaparin, or other heparins: a. Allergy (or hypersensitivity) to heparin, tinzaparin, other LMWHs, or pork products. b. History or presence of heparin-induced (type II) thrombocytopenia. c. Have or have had an epidural catheter or a traumatic spinal puncture within the previous 7 days. 2. Prothrombin time (PT) (International normalized ratio [INR] >1.5 for any reason) or aPTT >2 times control value. 3. Active or recent (<3 months) major bleeding or conditions predisposing to major bleeding. A major bleeding is defined as one that meets one of the following three criteria: a. occurring in a critical area or organ (for example, intracranial, intra-spinal, intraocular, retroperitoneal, intra-articular or pericardial, intrauterine or intramuscular with compartment syndrome), b. causing a decrease in hemoglobin levels of 2 g/l (1.24 mmol/l) or more, or c. that requires a transfusion of two or more units of whole blood or packed red blood cells. 4. Lesions or conditions at increased risk of clinically significant bleeding, including: a. Previously diagnosed/treated VTE 28 days prior to randomization. b. Active ulcer disease. c. Diagnosed cerebral metastases. d. Stroke within the prior 6 months. e. History of central nervous system (CNS) or intraocular bleeding. 5. Requirement of other anticoagulant therapy, dual antiplatelet therapy, daily non-steroidal anti-inflammatory drugs, or other medications known to increase the risk of bleeding. Note: A daily dose of 100 mg of aspirin and single agent clopidogrel are permitted 6. Acute or chronic renal insufficiency with Creatinine clearance < 30 ml / min. 7. Platelet count < 80.000 /l at the time of inclusion. 8. Severe liver insufficiency as defined by clinical manifestations of ascites, cirrhosis, encephalopathy and/or jaundice and/or biochemical abnormalities in liver function tests including: a. elevated levels of total bilirubin (> 2 times the upper limit normal [ULN]), b. elevated liver transaminases ALT or AST (> 2 times the ULN; > 5 in case of hepatic metastasis). 9. Participating in another study of an investigational agent at the time of enrollment. Note: Use of an experimental regimen of an approved product is not cause for exclusion. 10. Patients who weigh < 50 Kg. 11. Women of childbearing potential (WOCBP), must provide a negative serum or urine pregnancy test at screening. Women breastfeeding are not eligible. Note: A pregnancy test is performed on WOCBP as per standard of care for patients undergoing anticancer treatments. 12. Any underlying medical or psychiatric disorder, which, in the opinion of the investigator, makes the administration of tinzaparin unsafe or interferes with the informed consent process or trial procedures.

Calendario

(Última actualización: 27/01/2026)

Autorización 11/10/2022	Inicio de Ensayo 28/02/2023	Inclusión Primer Paciente 02/03/2023	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento 23/01/2025	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España 04/06/2025	Fin del ensayo global No aportado

Promotor

Grupo Gallego De Investigacion En Tumores Digestivos Spain

Rua De Ramon Y Cajal Num. 2

Contact Person

A person designed by the Sponsor

934344412

investigacion@mfar.net

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

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915867007

Centros

No iniciado (---/---/----)	Area Sanitaria De Ferrol Ferrol CORUÑA Oncology
No iniciado (22/09/2023)	Complejo Asistencial de Zamora Zamora ZAMORA Oncología
No iniciado (---/---/----)	Complejo Asistencial De Zamora Hospital Provincial De Zamora Zamora ZAMORA Oncology
Activo (07/11/2023)	Complejo Asistencial Universitario De Salamanca Salamanca SALAMANCA Medical Oncology
No iniciado (---/---/----)	Complejo Hospitalario Universitario De Ourense Ourense OURENSE Oncology
Activo (12/04/2023)	COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA Coruña, A CORUÑA Medical Oncology Department
Activo (28/02/2023)	COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE Ourense OURENSE Medical Oncology
Activo (07/06/2023)	COMPLEXO HOSPITALARIO UNIVERSITARIO DE PONTEVEDRA Pontevedra PONTEVEDRA Medical Oncology

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

Complejo Hospitalario Universitario De Pontevedra

Pontevedra

PONTEVEDRA

Oncology

Activo (14/04/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Medical Oncology Department

Activo (08/05/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

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Activo (21/03/2023)

EMPRESA PUBLICA HOSPITAL DEL SUR HOSPITAL INFANTA CRISTINA

Madrid

MADRID

Medical Oncology Department

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

Fundacion Centro Oncologico Regional De Galicia Jose Antonio Quiroga Y Pineyro

A Coruna

CORUÑA

Oncology

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

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Oncology

Activo (12/07/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Medical Oncology

Activo (11/04/2023)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Medical Oncology Department

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

Hospital Costa Del Sol

Marbella

MÁLAGA

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

Hospital De Jerez De La Frontera

Jerez De La Frontera

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HOSPITAL DE SABADELL

Sabadell

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Medical Oncology Department

Activo (10/11/2023)

HOSPITAL GENERAL LA MANCHA CENTRO

Alcázar de San Juan

CIUDAD REAL

Medical Oncology

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

Hospital General La Mancha Centro

Alcazar De San Juan

CIUDAD REAL

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

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

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Oncology

Activo (24/01/2024)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Oncología

Activo (22/06/2023)

HOSPITAL OBISPO POLANCO

Teruel

TERUEL

Medical Oncology Department

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

Hospital Obispo Polanco

Teruel

TERUEL

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

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Activo (13/06/2023)

HOSPITAL RIBERA POVISA

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Activo (31/03/2023)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

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HOSPITAL UNIVERSITARI SON ESPASES

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Activo (16/10/2023)

HOSPITAL UNIVERSITARIO ARQUITECTO MARCIDE

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Medical Oncology

Activo (16/05/2023)

HOSPITAL UNIVERSITARIO CLINICO SAN CARLOS

Madrid

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Medical Oncology

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

Hospital Universitario De Guadalajara SESCOAM

Guadalajara

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Activo (09/05/2023)

HOSPITAL UNIVERSITARIO DE JEREZ DE LA FRONTERA

Jerez de la Frontera

CÁDIZ

Medical Oncology

Activo (19/06/2023)

HOSPITAL UNIVERSITARIO DE MOSTOLES

Móstoles

MADRID

Medical Oncology Department

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

Hospital Universitario De Mostoles

Mostoles

MADRID

Oncology

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

Hospital Universitario De Toledo

Toledo

TOLEDO

Oncology

Cerrado (07/01/2026)

HOSPITAL UNIVERSITARIO DE TOLEDO (HUT)

Toledo

TOLEDO

Medical Oncology

No iniciado (11/10/2022)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

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Medical Oncology Department

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

Hospital Universitario Infanta Cristina

Parla

MADRID

Oncology

Activo (22/02/2024)

HOSPITAL UNIVERSITARIO INFANTA ELENA

Valdemoro

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Hospital Universitario Infanta Elena

Madrid

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Lugo

LUGO

Medical Oncology

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Hospital Universitario Lucus Augusti

Lugo

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HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

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HOSPITAL UNIVERSITARIO PRINCIPE DE ASTURIAS

Alcalá de Henares

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Medical Oncology Department

Activo (13/09/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

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Medical Oncology

Activo (04/05/2023)

HOSPITAL VIRGEN DE LA LUZ

Cuenca

CUENCA

Medical Oncology Department

Activo (27/03/2023)

HOSPITAL VIRGEN DE LOS LIRIOS

Alcoy/Alcoi

ALICANTE

Medical Oncology Department

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

Hospital Virgen De Los Lirios

Alcoy

ALICANTE

Oncology

Activo (22/05/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Medical Oncology

Activo (07/03/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medical Oncology Department

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

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Oncology

Medicamentos

**innohep 8.000 UI anti-Xa/0,4 ml
solución inyectable en jeringas
precargadas**

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

Código ATC: B01AB10 - TINZAPARINA
Principios Activos: N/A

Experimental

**innohep 4.500 UI anti-Xa/0,45 ml
solución inyectable en jeringas
precargadas**

SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
SUBCUTANEOUS INJECTION

Código ATC: B01AB10 - TINZAPARINA
Principios Activos: N/A

Experimental

Sin resultados

Prophylaxis of venous thromboembolic disease with LMWH (TINzaparin) in patients with metastatic colorectal cancer who start the first line of treatment.

State
Finished CT

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase III

Expected Participants
526

Results
No results

Low level of intervention
Yes

Rare disease
No

Geographic coverage
National multicenter

Areas of the study
prophylaxis

Advanced therapy
NO

Information

Identifier
2023-508860-31-00 (CTIS)

Protocol Code
GIT-PR0-2022-02

Transitioned 2022-001534-11

Therapeutic area

- Not possible to specify
- Diseases [C] - Cardiovascular Diseases [C14]
- Diseases [C] - Cancer [C04]

Investigated Disease

Stage IV colon or rectal adenocarcinoma (mCRC).

Scientific Title

Prophylaxis of venous thromboembolic disease with LMWH (TINzaparin) in patients with metastatic colorectal cancer who start the first line of treatment.

Rationale

Not provided

Main Objective

The main objective of the study is to evaluate the efficacy of 4-months prophylaxis with LMWH (tinzaparin) for the prevention of symptomatic or incidental VTE events in patients with stage IV colorectal cancer (mCRC) that initiate first line systemic treatment (ChT +/- targeted therapy).

Primary Endpoints

The primary efficacy endpoint is the cumulative incidence of any VTE event including: Symptomatic non-fatal pulmonary thromboembolism (PE). Symptomatic lower-limb deep vein thromboembolism (sIIDVT). Symptomatic upper extremity deep vein thromboembolism (sueDVT). Incidentally diagnosed PE or proximal DVT. Symptomatic central venous catheter thromboembolism. Incidentally visceral vein thrombosis (iVVT). Symptomatic visceral vein thrombosis (sVVT). VTE-related deaths

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male or female subjects with age 18 years. 2. Written informed consent. 3. Patients with a histologically confirmed diagnosis of stage IV colon or rectal adenocarcinoma (mCRC). 4. Locally assessed BRAF and RAS genomic alterations available during screening. 5. Beginning of the first line of treatment for metastatic disease with chemotherapy +/- targeted therapy (i.e. antiangiogenic, anti-EGFR, encorafenib-cetuximab doublet) or

immunotherapy. 6. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. 7. Life expectancy >6 months.

Exclusion criteria

1. Contraindication to tinzaparin, or other heparins: a. Allergy (or hypersensitivity) to heparin, tinzaparin, other LMWHs, or pork products. b. History or presence of heparin-induced (type II) thrombocytopenia. c. Have or have had an epidural catheter or a traumatic spinal puncture within the previous 7 days. 2. Prothrombin time (PT) (International normalized ratio [INR] >1.5 for any reason) or aPTT >2 times control value. 3. Active or recent (<3 months) major bleeding or conditions predisposing to major bleeding. A major bleeding is defined as one that meets one of the following three criteria: a. occurring in a critical area or organ (for example, intracranial, intra-spinal, intraocular, retroperitoneal, intra-articular or pericardial, intrauterine or intramuscular with compartment syndrome), b. causing a decrease in hemoglobin levels of 2 g/l (1.24 mmol/l) or more, or c. that requires a transfusion of two or more units of whole blood or packed red blood cells. 4. Lesions or conditions at increased risk of clinically significant bleeding, including: a. Previously diagnosed/treated VTE 28 days prior to randomization. b. Active ulcer disease. c. Diagnosed cerebral metastases. d. Stroke within the prior 6 months. e. History of central nervous system (CNS) or intraocular bleeding. 5. Requirement of other anticoagulant therapy, dual antiplatelet therapy, daily non-steroidal anti-inflammatory drugs, or other medications known to increase the risk of bleeding. Note: A daily dose of 100 mg of aspirin and single agent clopidogrel are permitted 6. Acute or chronic renal insufficiency with Creatinine clearance < 30 ml / min. 7. Platelet count < 80.000 /l at the time of inclusion. 8. Severe liver insufficiency as defined by clinical manifestations of ascites, cirrhosis, encephalopathy and/or jaundice and/or biochemical abnormalities in liver function tests including: a. elevated levels of total bilirubin (> 2 times the upper limit normal [ULN]), b. elevated liver transaminases ALT or AST (> 2 times the ULN; > 5 in case of hepatic metastasis). 9. Participating in another study of an investigational agent at the time of enrollment. Note: Use of an experimental regimen of an approved product is not cause for exclusion. 10. Patients who weigh < 50 Kg. 11. Women of childbearing potential (WOCBP), must provide a negative serum or urine pregnancy test at screening. Women breastfeeding are not eligible. Note: A pregnancy test is performed on WOCBP as per standard of care for patients undergoing anticancer treatments. 12. Any underlying medical or psychiatric disorder, which, in the opinion of the investigator, makes the administration of tinzaparin unsafe or interferes with the informed consent process or trial procedures.

Calendar

(Last Update: 27/01/2026)

Authorization 11/10/2022	Start of Trial 28/02/2023	First patient inclusion 02/03/2023	Halted Not aported	Restarted Not aported
End of recruitment 23/01/2025	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) 04/06/2025	Trial end (Global) Not aported

Sponsor

Grupo Gallego De Investigacion En Tumores Digestivos Spain

Rua De Ramon Y Cajal Num. 2

Contact Person

A person designed by the Sponsor

934344412

investigacion@mfar.net

Monetary support: N/A

Sponsor type: Commercial

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Sites

not initialized (---/---/----)	Area Sanitaria De Ferrol Ferrol CORUÑA Oncology
not initialized (22/09/2023)	Complejo Asistencial de Zamora Zamora ZAMORA Oncología
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Active (07/11/2023)	Complejo Asistencial Universitario De Salamanca Salamanca SALAMANCA Medical Oncology
not initialized (---/---/----)	Complejo Hospitalario Universitario De Ourense Ourense OURENSE Oncology
Active (12/04/2023)	COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA Coruña, A CORUÑA Medical Oncology Department
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Active (14/04/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

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CORUÑA

Medical Oncology Department

Active (08/05/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

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EMPRESA PUBLICA HOSPITAL DEL SUR HOSPITAL INFANTA CRISTINA

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A Coruna

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Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Oncology

Active (12/07/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Medical Oncology

Active (11/04/2023)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Medical Oncology Department

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

Hospital Costa Del Sol

Marbella

MÁLAGA

Oncology

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Hospital De Jerez De La Frontera

Jerez De La Frontera

CÁDIZ

Oncology

Active (22/03/2023)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

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Medical Oncology Department

Active (22/03/2023)

HOSPITAL DE SABADELL

Sabadell

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Medical Oncology Department

Active (10/11/2023)

HOSPITAL GENERAL LA MANCHA CENTRO

Alcázar de San Juan

CIUDAD REAL

Medical Oncology

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Hospital General La Mancha Centro

Alcazar De San Juan

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Hospital General Universitario De Valencia

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Hospital General Universitario Morales Mesguer

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Hospital General Universitario Morales Meseguer

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TERUEL

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Medical Oncology

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Hospital Universitari Arnau De Vilanova De La Gerencia Territorial De Lleida

Lleida

LÉRIDA

Oncology

Active (31/03/2023)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

Medical Oncology Department

Active (28/03/2023)

HOSPITAL UNIVERSITARI SON ESPASES

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Active (16/10/2023)

HOSPITAL UNIVERSITARIO ARQUITECTO MARCIDE

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Medical Oncology

Active (16/05/2023)

HOSPITAL UNIVERSITARIO CLINICO SAN CARLOS

Madrid

MADRID

Medical Oncology

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Hospital Universitario De Guadalajara SESCAM

Guadalajara

GUADALAJARA

Oncology

Active (09/05/2023)

HOSPITAL UNIVERSITARIO DE JEREZ DE LA FRONTERA

Jerez de la Frontera

CÁDIZ

Medical Oncology

Active (19/06/2023)

HOSPITAL UNIVERSITARIO DE MOSTOLES

Móstoles

MADRID

Medical Oncology Department

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Hospital Universitario De Mostoles

Mostoles

MADRID

Oncology

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Hospital Universitario De Toledo

Toledo

TOLEDO

Oncology

Closed (07/01/2026)

HOSPITAL UNIVERSITARIO DE TOLEDO (HUT)

Toledo

TOLEDO

Medical Oncology

not initialized (11/10/2022)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

MADRID

Medical Oncology Department

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Hospital Universitario Infanta Cristina

Parla

MADRID

Oncology

Active (22/02/2024)

HOSPITAL UNIVERSITARIO INFANTA ELENA

Valdemoro

MADRID

Medical Oncology Department

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Hospital Universitario Infanta Elena

Madrid

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Active (19/04/2023)

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Hospital Universitario Lucus Augusti

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Oncology

Active (09/05/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Medical Oncology

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Sevilla

SEVILLA

Medical Oncology Department

Active (13/09/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

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Medical Oncology

Active (04/05/2023)

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Active (27/03/2023)

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BARCELONA

Oncology

Medication

**innohep 8.000 UI anti-Xa/0,4 ml
solución inyectable en jeringas
precargadas**

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

ATC code: B01AB10 - TINZAPARINA

Active Principles: N/A

Experimental

**innohep 4.500 UI anti-Xa/0,45 ml
solución inyectable en jeringas
precargadas**

SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
SUBCUTANEOUS INJECTION

ATC code: B01AB10 - TINZAPARINA

Active Principles: N/A

Experimental

No results