Study to evaluate the efficacy and safety of enoxaparin in children with slow-flow vascular problems undergoing interventional procedures

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	60
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	Si	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	seguridad, eficacia	NO

Información

Identificador
2025-521196-32-00 (CTIS)

Cod. Protocolo
FSJD-PEaRL-X-2025

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Venous malformation or low-flow venous/lymphatic malformation

Título Científico
Phase III, randomized, open-label, single-site clinical trial to evaluate the efficacy and safety of enoxaparin as a prophylactic treatment for localized intravascular coagulopathy and the impact of endothelial damage markers in patients aged 0 to 18 years with slow-flow vascular malformations undergoing percutaneous interventional procedures (PEaRL-X)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy and safety of enoxaparin in the prevention of localized intravascular coagulopathy and its complications during percutaneous interventional procedures in pediatric patients with slow-flow vascular malformations.

Variables de Evaluación Primaria

1. Values of localized intravascular coagulopathy and endothelial damage in patients receiving/not receiving prophylactic treatment with enoxaparin.
2. Hemorrhagic clinical signs related to treatment through: Subjective assessment of bleeding Hemoglobin levels Classification of haemorrhage

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To describe baseline parameters of slow-flow intravascular coagulopathy and markers of endothelial damage in a pediatric population of patients with slow-flow vascular malformations undergoing percutaneous interventional procedures.
2. To identify risk factors associated with severe baseline localized intravascular coagulopathy parameters.
3. To evaluate whether the use of prophylactic doses of enoxaparin is useful in improving slow-flow intravascular coagulopathy parameters, endothelial damage markers, reducing episodes of pain, and deep vein thrombosis during percutaneous interventional procedures.

Variables de Evaluación Secundaria

1. Baseline analytical parameters of localized intravascular coagulopathy and endothelial damage.
2. Values of localized intravascular coagulopathy (D-dimer, fibrinogen, platelets) in relation to possible risk factors: age, characteristics and extent of the malformation, genetic diagnosis, and bone/muscular/visceral involvement.
3. Analytical parameters of localized intravascular coagulopathy and endothelial damage in relation to the degree of inflammation, pain presented by patients after the intervention, appearance of new phleboliths, or development of deep vein thrombosis during the study period.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Patients aged 018 years with a diagnosis of venous or low-flow venous/lymphatic malformation.
2. Scheduled percutaneous invasive procedure during the study period: sclerotherapy, cryoablation, or electroporation.
3. Signed informed consent from the patient, parents, or legal guardians (and assent for patients 12 years).

Criterios de Exclusión

1. Patients on active anticoagulant treatment. 10. Glomerular filtration rate < 30 ml/m²/min calculated using the Schwartz formula. 11. Alanine aminotransferase: 0 - 1 day of life > 165 U/L 1 day - 1 month of life > 210 U/L 1 - 3 months of life > 185 U/L 3 - 9 months of life > 165 U/L 9 months - 12 years of life > 155 U/L 12 - 18 years of life > 150 U/L 12. Aspartate aminotransferase: 0 - 1 day of life > 475 U/L 1 day - 1 month of life > 385 U/L 1 - 2 months of life > 315 U/L 2 - 9 months of life > 280 U/L 9 months - 6 years of life > 250 U/L 6 - 18 years of life > 190 U/L 13. Total bilirubin: 0 - 1 day of life > 17.91 mg/dL 1 - 2 days of life > 20.88 mg/dL 2 - 5 days of life > 17.91 mg/dL 5 days - 1 year of life > 2.97 mg/dL 1 - 18 years of life > 2.97 mg/dL 14. Uncontrolled arterial hypertension. 15. Pregnancy or breastfeeding. 16. Psychological or cognitive disorders that prevent treatment administration or inability to attend scheduled study visits. 17. Simultaneous participation in another clinical trial with medication. 2. Known allergy or hypersensitivity to enoxaparin. 3. History of heparin-induced thrombocytopenia. 4. Presence of severe unrelated disease that prevents the procedure or administration of enoxaparin. 5. Thrombocytopenia < 50,000/mm³. 6. Active or recent bleeding (severe gastrointestinal bleeding with hemodynamic compromise or urgent need for intervention, or cerebral hemorrhage in the last 3 months). 7. Spinal or epidural anesthesia or locoregional anesthesia within 24 hours prior to study treatment. 8. Major surgery or severe trauma in the last 4 weeks. 9. Scheduled lumbar puncture during the study.

Calendario

(Última actualización: 01/12/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/07/2025	12/09/2025	31/10/2025	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

Fundacio Sant Joan De Deu Spain

Calle Santa Rosa 39-57 3a Planta

Contact Person

Dr. Rubén Berrueco

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

Dermatology area

Medicamentos

Enoxaparina Rovi 6.000 UI (60 mg)/0,6 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B01AB05 - ENOXAPARINA
Principios Activos: N/A

Experimental

Enoxaparina Rovi 2.000 UI (20 mg)/0,2 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B01AB05 - ENOXAPARINA
Principios Activos: N/A

Experimental

Enoxaparina Rovi 10.000 UI (100 mg)/1 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B01AB05 - ENOXAPARINA
Principios Activos: N/A

Experimental

Enoxaparina Rovi 4.000 UI (40 mg)/0,4 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B01AB05 - ENOXAPARINA
Principios Activos: N/A

Experimental

Enoxaparina Rovi 8.000 UI (80 mg)/0,8 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B01AB05 - ENOXAPARINA
Principios Activos: N/A

Experimental

Sin resultados

Study to evaluate the efficacy and safety of enoxaparin in children with slow-flow vascular problems undergoing interventional procedures

State	**Type of participants**	**Age Ranges**
Recruiting	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	60
Results	**Low level of intervention**	**Rare disease**
No results	Yes	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	safety, effectiveness	NO

Information

Identifier
2025-521196-32-00 (CTIS)

Protocol Code
FSJD-PEaRL-X-2025

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Venous malformation or low-flow venous/lymphatic malformation

Scientific Title
Phase III, randomized, open-label, single-site clinical trial to evaluate the efficacy and safety of enoxaparin as a prophylactic treatment for localized intravascular coagulopathy and the impact of endothelial damage markers in patients aged 0 to 18 years with slow-flow vascular malformations undergoing percutaneous interventional procedures (PEaRL-X)

Rationale

Not provided

Main Objective

To evaluate the efficacy and safety of enoxaparin in the prevention of localized intravascular coagulopathy and its complications during percutaneous interventional procedures in pediatric patients with slow-flow vascular malformations.

Primary Endpoints

1. Values of localized intravascular coagulopathy and endothelial damage in patients receiving/not receiving prophylactic treatment with enoxaparin.
2. Hemorrhagic clinical signs related to treatment through: Subjective assessment of bleeding Hemoglobin levels Classification of haemorrhage

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To describe baseline parameters of slow-flow intravascular coagulopathy and markers of endothelial damage in a pediatric population of patients with slow-flow vascular malformations undergoing percutaneous interventional procedures.
2. To identify risk factors associated with severe baseline localized intravascular coagulopathy parameters.
3. To evaluate whether the use of prophylactic doses of enoxaparin is useful in improving slow-flow intravascular coagulopathy parameters, endothelial damage markers, reducing episodes of pain, and deep vein thrombosis during percutaneous interventional procedures.

Secondary Endpoints

1. Baseline analytical parameters of localized intravascular coagulopathy and endothelial damage.
2. Values of localized intravascular coagulopathy (D-dimer, fibrinogen, platelets) in relation to possible risk factors: age, characteristics and extent of the malformation, genetic diagnosis, and bone/muscular/visceral involvement.
3. Analytical parameters of localized intravascular coagulopathy and endothelial damage in relation to the degree of inflammation, pain presented by patients after the intervention, appearance of new phleboliths, or development of deep vein thrombosis during the study period.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Patients aged 018 years with a diagnosis of venous or low-flow venous/lymphatic malformation.
2. Scheduled percutaneous invasive procedure during the study period: sclerotherapy, cryoablation, or electroporation.
3. Signed informed consent from the patient, parents, or legal guardians (and assent for patients 12 years).

Exclusion criteria

1. Patients on active anticoagulant treatment. 10. Glomerular filtration rate < 30 ml/m²/min calculated using the Schwartz formula. 11. Alanine aminotransferase: 0 - 1 day of life > 165 U/L 1 day - 1 month of life > 210 U/L 1 - 3 months of life > 185 U/L 3 - 9 months of life > 165 U/L 9 months - 12 years of life > 155 U/L 12 - 18 years of life > 150 U/L 12. Aspartate aminotransferase: 0 - 1 day of life > 475 U/L 1 day - 1 month of life > 385 U/L 1 - 2 months of life > 315 U/L 2 - 9 months of life > 280 U/L 9 months - 6 years of life > 250 U/L 6 - 18 years of life > 190 U/L 13. Total bilirubin: 0 - 1 day of life > 17.91 mg/dL 1 - 2 days of life > 20.88 mg/dL 2 - 5 days of life > 17.91 mg/dL 5 days - 1 year of life > 2.97 mg/dL 1 - 18 years of life > 2.97 mg/dL 14. Uncontrolled arterial hypertension. 15. Pregnancy or breastfeeding. 16. Psychological or cognitive disorders that prevent treatment administration or inability to attend scheduled study visits. 17. Simultaneous participation in another clinical trial with medication. 2. Known allergy or hypersensitivity to enoxaparin. 3. History of heparin-induced thrombocytopenia. 4. Presence of severe unrelated disease that prevents the procedure or administration of enoxaparin. 5. Thrombocytopenia < 50,000/mm³. 6. Active or recent bleeding (severe gastrointestinal bleeding with hemodynamic compromise or urgent need for intervention, or cerebral hemorrhage in the last 3 months). 7. Spinal or epidural anesthesia or locoregional anesthesia within 24 hours prior to study treatment. 8. Major surgery or severe trauma in the last 4 weeks. 9. Scheduled lumbar puncture during the study.

Calendar

(Last Update: 01/12/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/07/2025	12/09/2025	31/10/2025	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

Fundacio Sant Joan De Deu Spain

Calle Santa Rosa 39-57 3a Planta

Contact Person

Dr. Rubén Berrueco

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

Dermatology area

Medication

Enoxaparina Rovi 6.000 UI (60 mg)/0,6 ml solución inyectable en jeringa precargada

SOLUTION FOR INJECTION
SUBCUTANEOUS

ATC code: B01AB05 - ENOXAPARINA
Active Principles: N/A

Experimental

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SOLUTION FOR INJECTION
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SUBCUTANEOUS

ATC code: B01AB05 - ENOXAPARINA
Active Principles: N/A

Experimental

No results