IMPACT OF INTRAVENOUS IRON TREATMENT OF PREOPERATIVE ANEMIA IN PATIENTS WITH LOWER EXTREMITY PERIPHERAL ARTERY DISEASE (IRONPAD)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	240
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	Si	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	profilaxis, tratamiento	NO

Información

Identificador
2024-514593-50-00 (CTIS)

Cod. Protocolo
IRONPAD

Transicionado 2018-003714-40

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

Enfermedad investigada
Anemia in patients with chronic ischemia of the lower limb ischemia

Título Científico
IMPACT OF INTRAVENOUS IRON TREATMENT OF PREOPERATIVE ANEMIA IN PATIENTS WITH LOWER EXTREMITY PERIPHERAL ARTERY DISEASE (IRONPAD)

Justificación

No aportado

Objetivo Principal

Reduce the incidence of transfusion from randomization up to 30 days after the main surgery in patients with anemia who undergo revascularization surgery with chronic lower limb ischemia

Variables de Evaluación Primaria

Reduce the incidence of transfusion from randomization up to 30 days after the main surgery in patients with anemia who undergo revascularization surgery with chronic lower limb ischemia

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

-Changes and evolution of hemoglobin during admission; difference in hemoglobin (Hb) between inclusion, intervention and discharge. Hb 30 days after discharge -Establish the optimal preoperative moment of increased intravenous iron yield to increase Hb -Impact of anemia and its treatment on the length of hospital stay, morbidity and mortality and quality of life during admission and first 30 days postoperatively

Variables de Evaluación Secundaria

- Establish the optimal preoperative time of highest yield of iv iron to increase HB. - Changes and evolution of hemoglobin during admission; difference in Hb between inclusion, intervention and discharge. Hb 30 days after discharge. - Impact of anemia and its treatment on length of hospital stay, morbimortality and quality of life during admission and first 30 postoperative days

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

-Patients of both sexes over 18 years of age. years of age. - Diagnosed with anemia, considered as as Hb <13.0 g/dL in men and Hb<12g/dL in women. in women. - Diagnosed with chronic ischemia of MMII ischemia (Rutherford-

Baker grades 2-5, both included; Fontaine grades II-IV), who are going to undergo who are to undergo surgical revascularization (endovascular or open) and who accept the treatment. treatment. - Planned revascularization surgery in the approximate minimum period of time, > 48 hours to 3 weeks, from inclusion. - Patients diagnosed with iron deficiency iron deficiency anemia under treatment with oral iron in their usual medication and with an inadequate iron inadequate iron deposit for a surgical intervention (ferritin (ferritin <100 ng/ml) or functional ferropenia: ferritin functional: ferritin 100-500 ng/ml with IST < 20%. - Who are able and willing to give written informed written informed consent at the time of at the time of screening.

Criterios de Exclusión

- Patients with acute ischemia will be excluded. - Severe anemia < 8 g/dL. - Arterial hypertension not controlled with antihypertensive medication (considered with systolic pressure >180mmHg or diastolic >100mmHg). - Acute renal failure or renal insufficiency with creatinine clearance <30mmHg. - Patient with documented intolerance or allergy to iron or its derivatives. - Unstable angina, defined as electrocardiographic changes with chest pain indicating myocardial ischemia at rest. - History of stroke in the previous 6 months. - Patients with thrombocytopenia of less than 50,000ug/dl or coagulation alterations. - Simultaneously participating in a clinical trial that conditions or modifies the registry. - Pregnancy or lactation (pregnancy tests in women of childbearing age according to standard practice). - Refusal of treatment or inclusion in the registry by the patient. - Patients refusing blood product transfusions (e.g. Jehovah's Witnesses). - Patients with SEPSIS criteria. - Patients with Ferritin <30 ng/mL who will be referred for digestive study. - Patients with active neoplasia. - Patients who are not able to give informed consent or understand the study procedure. - Probable or confirmed case with active SARS-CoV-2 infection. - Considering probable infection as: person with severe acute respiratory infection with clinical and radiological picture compatible with COVID-19 and negative PDIA results, or suspected cases with inconclusive PDIA. -Confirmed case with active SARS-CoV-2 infection: - Person meeting suspect case criteria and with positive PDIA. - Person who meets the criteria of a suspected case, with negative PDIA and positive IgM result by high-throughput serology. - Asymptomatic person with a positive PDIA with negative IgG or not performed. o Suspect case is defined as: any person with a clinical picture of acute respiratory infection of sudden onset with of sudden onset acute respiratory infection of any severity presenting with, among others, fever, cough or shortness of breath, with fever, cough or shortness of breath. - Other symptoms such as odynophagia, anosmia, ageusia, muscle pain, diarrhea, chest pain or headache, among others, may also be considered symptoms of suspected SARS-CoV-2 infection according to clinical criteria.

Calendario

(Última actualización: 04/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/04/2019	No aportado	28/08/2019	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

Asociacion Instituto De Investigacion Sanitaria Biobizkaia Spain

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Contact Person

REGULATORIA

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Monetary support: N/A

Tipo de promotor: Comercial

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VIZCAYA/BIZKAIA

CIRUGIA VASCULAR Y ANGIOLOGIA

Cerrado (01/12/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

CIRUGIA VASCULAR Y ANGIOLOGIA

Activo (15/08/2019)

HOSPITAL UNIVERSITARIO DE CRUCES

Barakaldo

VIZCAYA/BIZKAIA

Vascular Surgery Department

Cerrado (01/12/2025)

Hospital Universitario De Getafe

Getafe

MADRID

CIRUGIA VASCULAR Y ANGIOLOGIA

Activo (01/12/2025)

Hospital Universitario La Paz

Madrid

MADRID

CIRUGIA VASCULAR Y ANGIOLOGIA

Medicamentos

Ferinject 50 mg/ml dispersión inyectable y para perfusión

DISPERSION FOR INJECTION/INFUSION

INTRAVENOUS USE

Código ATC: B03AC - HIERRO, PREPARADOS PARENTERALES

Principios Activos: N/A

Experimental

Sin resultados

IMPACT OF INTRAVENOUS IRON TREATMENT OF PREOPERATIVE ANEMIA IN PATIENTS WITH LOWER EXTREMITY PERIPHERAL ARTERY DISEASE (IRONPAD)

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase IV	240
Results	**Low level of intervention**	**Rare disease**
No results	Yes	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	prophylaxis, treatment	NO

Information

Identifier
2024-514593-50-00 (CTIS)

Protocol Code
IRONPAD

Transitioned 2018-003714-40

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

Investigated Disease
Anemia in patients with chronic ischemia of the lower limb ischemia

Scientific Title
IMPACT OF INTRAVENOUS IRON TREATMENT OF PREOPERATIVE ANEMIA IN PATIENTS WITH LOWER EXTREMITY PERIPHERAL ARTERY DISEASE (IRONPAD)

Rationale

Not provided

Main Objective

Reduce the incidence of transfusion from randomization up to 30 days after the main surgery in patients with anemia who undergo revascularization surgery with chronic lower limb ischemia

Primary Endpoints

Reduce the incidence of transfusion from randomization up to 30 days after the main surgery in patients with anemia who undergo revascularization surgery with chronic lower limb ischemia

Temporary moments of secondary assessment

Not provided

Secondary Objective

-Changes and evolution of hemoglobin during admission; difference in hemoglobin (Hb) between inclusion, intervention and discharge. Hb 30 days after discharge -Establish the optimal preoperative moment of increased intravenous iron yield to increase Hb -Impact of anemia and its treatment on the length of hospital stay, morbidity and mortality and quality of life during admission and first 30 days postoperatively

Secondary Endpoints

- Establish the optimal preoperative time of highest yield of iv iron to increase HB. - Changes and evolution of hemoglobin during admission; difference in Hb between inclusion, intervention and discharge. Hb 30 days after discharge. - Impact of anemia and its treatment on length of hospital stay, morbimortality and quality of life during admission and first 30 postoperative days

Temporary moments of secondary assessment

Not provided

Inclusion criteria

-Patients of both sexes over 18 years of age. years of age. - Diagnosed with anemia, considered as as Hb <13.0 g/dL in men and Hb<12g/dL in women. in women. - Diagnosed with chronic ischemia of MMII ischemia (Rutherford-

Baker grades 2-5, both included; Fontaine grades II-IV), who are going to undergo who are to undergo surgical revascularization (endovascular or open) and who accept the treatment. treatment. - Planned revascularization surgery in the approximate minimum period of time, > 48 hours to 3 weeks, from inclusion. - Patients diagnosed with iron deficiency iron deficiency anemia under treatment with oral iron in their usual medication and with an inadequate iron inadequate iron deposit for a surgical intervention (ferritin (ferritin <100 ng/ml) or functional ferropenia: ferritin functional: ferritin 100-500 ng/ml with IST < 20%. - Who are able and willing to give written informed written informed consent at the time of at the time of screening.

Exclusion criteria

- Patients with acute ischemia will be excluded. - Severe anemia < 8 g/dL. - Arterial hypertension not controlled with antihypertensive medication (considered with systolic pressure >180mmHg or diastolic >100mmHg). - Acute renal failure or renal insufficiency with creatinine clearance <30mmHg. - Patient with documented intolerance or allergy to iron or its derivatives. - Unstable angina, defined as electrocardiographic changes with chest pain indicating myocardial ischemia at rest. - History of stroke in the previous 6 months. - Patients with thrombocytopenia of less than 50,000ug/dl or coagulation alterations. - Simultaneously participating in a clinical trial that conditions or modifies the registry. - Pregnancy or lactation (pregnancy tests in women of childbearing age according to standard practice). - Refusal of treatment or inclusion in the registry by the patient. - Patients refusing blood product transfusions (e.g. Jehovah's Witnesses). - Patients with SEPSIS criteria. - Patients with Ferritin <30 ng/mL who will be referred for digestive study. - Patients with active neoplasia. - Patients who are not able to give informed consent or understand the study procedure. - Probable or confirmed case with active SARS-CoV-2 infection. - Considering probable infection as: person with severe acute respiratory infection with clinical and radiological picture compatible with COVID-19 and negative PDIA results, or suspected cases with inconclusive PDIA. -Confirmed case with active SARS-CoV-2 infection: - Person meeting suspect case criteria and with positive PDIA. - Person who meets the criteria of a suspected case, with negative PDIA and positive IgM result by high-throughput serology. - Asymptomatic person with a positive PDIA with negative IgG or not performed. o Suspect case is defined as: any person with a clinical picture of acute respiratory infection of sudden onset with of sudden onset acute respiratory infection of any severity presenting with, among others, fever, cough or shortness of breath, with fever, cough or shortness of breath. - Other symptoms such as odynophagia, anosmia, ageusia, muscle pain, diarrhea, chest pain or headache, among others, may also be considered symptoms of suspected SARS-CoV-2 infection according to clinical criteria.

Calendar

(Last Update: 04/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/04/2019	Not aported	28/08/2019	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

Asociacion Instituto De Investigacion Sanitaria Biobizkaia Spain

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Medication

Ferinject 50 mg/ml dispersión inyectable y para perfusión

DISPERSION FOR INJECTION/INFUSION

INTRAVENOUS USE

ATC code: B03AC - HIERRO, PREPARADOS PARENTERALES

Active Principles: N/A

Experimental

No results