# 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

**Cruces Plaza 12**

**Contact Person**

REGULATORIA

**944526785**

**uiceecc.regulatoria@bio-bizkaia.eus**

**Monetary support: N/A**

**Tipo de promotor: Comercial**

# Ceim

### CEIm de Euskadi

**C/ Donostia-San Sebastián, nº 1. 01010 Vitoria-Gasteiz**

**ceic.eeaa@euskadi.eus**

**945019296**

# Centros

Activo (01/12/2025)

**Hospital De Galdakao Usansolo**

Galdakao

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-

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## Exclusion criteria

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# 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**

**Cruces Plaza 12**

**Contact Person**

REGULATORIA

**944526785**

**uiceecc.regulatoria@bio-bizkaia.eus**

**Monetary support: N/A**

**Sponsor type: Commercial**

# Ceim

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**ceic.eeaa@euskadi.eus**

**945019296**

# Sites

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Galdakao

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Closed (01/12/2025)

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INTRAVENOUS USE

ATC code: B03AC - HIERRO, PREPARADOS PARENTERALES

Active Principles: N/A

Experimental

# No results