

# European Observational Cohort Study of delayed union and non-union fractures of long bones. (COHORTHO-UNION)

**First published:** 19/05/2025

**Last updated:** 04/06/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000535

### Study ID

1000000535

### DARWIN EU® study

No

### Study countries

- France
- Germany
- Italy
- Spain

## Study status

Ongoing

## Research institutions and networks

### Institutions

[Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital \(HUPHM\)](#)

Spain

**First published:** 26/12/2012

**Last updated:** 20/08/2024

**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

[Hospital Universitario La Paz, Madrid. Spain](#)

[Musculoskeletal University Center, Munich.](#)

[Germany.](#)

[Universitätsklinikum Ulm. Germany.](#)

[Centre Hospitalier Régional Universitaire De Tours, Chambray Les Tours. France](#)

Hôpital Henri Mondor, Créteil. France.

Hôpital Antoine-Béclère, Clamart. France

Fondazione Policlinico Universitario Campus Bio-Medico, Rome. Italy

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan. Italy.

Istituto Ortopedico Rizzoli, Bologna. Italy.

OAU Policlinico “Gaetano Martino” di Messina. Italy

## Networks

European Clinical Research Infrastructure Network (ECRIN)

**First published:** 01/02/2024

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Network

## Contact details

## **Study institution contact**

Cristina Avendaño Solá [cristina.avendano@uam.es](mailto:cristina.avendano@uam.es)

[Study contact](#)

[cristina.avendano@uam.es](mailto:cristina.avendano@uam.es)

## **Primary lead investigator**

Enrique Gómez Barrena

[Primary lead investigator](#)

## Study timelines

### **Date when funding contract was signed**

Planned: 01/12/2023

Actual: 01/12/2023

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### **Study start date**

Planned: 02/09/2024

Actual: 06/08/2024

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### **Date of final study report**

Planned: 31/12/2028

## Sources of funding

- EU institutional research programme

## More details on funding

The Study is part of the ORTHO-ALLO-UNION European Consortium Agreement which receives funding from the European Union, Horizon Research and Innovation Action n° 101137464

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Medical procedure

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##### **Study type:**

Non-interventional study

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##### **Study design:**

A prospective-retrospective cohort study.

##### **Main study objective:**

This study aims to determine the effectiveness of treatments for achieving bone consolidation in delayed-union and non-union of long bone fractures.

## Study drug and medical condition

### **Medical condition to be studied**

Fracture delayed union

Fracture nonunion

## Population studied

### **Short description of the study population**

Any patient whose reason for intervention (index surgery) is delayed union or non-union after long bone fractures.

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### **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

## Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Yes

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

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## Data characterisation

### **Data characterisation conducted**

No