

European Observational Cohort Study of delayed union and non-union fractures of long bones. (COHORTH0-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

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Study contact

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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

Study start date

Planned: 02/09/2024

Actual: 06/08/2024

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Medical procedure

Study type:

Non-interventional study

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.

Age groups

- **Adult and elderly population (≥ 18 years)**

- Adults (18 to < 65 years)
 - Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
- Elderly (≥ 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

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No