DARWIN EU® - Descriptive study of tetanus immunoglobulin use and tetanus-prone wounds in Europe

First published: 29/07/2025

Last updated: 26/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000685

Study ID

1000000685

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Germany
- [ ] Netherlands
- [ ] Spain

United Kingdom

Study description

Tetanus is a rare but serious neurological condition caused by a neurotoxin from Clostridium tetani, typically introduced through contaminated wounds. Although vaccine-preventable, tetanus remains a public health concern due to the irreversible nature of the toxin once it enters neurons. Post-exposure prophylaxis, including wound care, tetanus immunoglobulin (TIG), and a booster vaccination, is critical for individuals with tetanus-prone injuries, depending on immunisation status.

In 2022, 53 cases were reported in the European Union (EU), underscoring the importance of timely and appropriate clinical intervention.

This study aims to generate real-world evidence on TIG prescribing patterns and the epidemiology of tetanus-prone wounds across Europe to support regulatory decision-making and inform clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ellen Gerritsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/03/2025

Actual: 24/06/2025

Study start date

Planned: 17/07/2025

Actual: 17/07/2025

Date of final study report

Planned: 24/11/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-002_Tetanus occurrence and management_V2.0.pdf (1000.45 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 6 data sources.

Main study objective:

Research question

What is the incidence and prevalence of tetanus immunoglobulins use and tetanus-prone wounds over time across Europe?

Study objectives

1. To estimate incidence, prevalence, and treatment rate of tetanus immunoglobulins use in the general population, overall and stratified by calendar year.

2. To estimate incidence rate and prevalence of tetanus-prone wounds in the general population, overall and stratified by calendar year and type of wound.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J06AA02) tetanus antitoxin

tetanus antitoxin

(J06BB02) tetanus immunoglobulin

tetanus immunoglobulin

Population studied

Short description of the study population

All individuals registered in the respective database between 1st of January 2017 and 31st of December 2023 (or latest date available). For estimation of incidence rates, individuals must have at least 1 year of data visibility prior to becoming eligible for study inclusion. However, no such requirement will be applied for prevalence and treatment rate analyses. Children aged <1 year of age will be excluded

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Age groups

All

Study design details

Setting

The study will be conducted using routinely collected data from 6 data sources in 6 European countries (5 EU countries and the United Kingdom).
All databases were previously mapped to the OMOP Common Data Model (CDM).

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.

Data sources

Data source(s)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)
Clinical Practice Research Datalink (CPRD) GOLD
Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)
InGef Research Database
Integrated Primary Care Information (IPCI)
Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable