# DARWIN EU® - Suicidality following exposure to doxycycline

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# Administrative details

| EU PAS number    |
|------------------|
| EUPAS1000000280  |
|                  |
| Study ID         |
| 100000280        |
| DARWIN EU® study |
| Yes              |
| Study countries  |
| Netherlands      |
| ☐ Spain          |
| United Kingdom   |

#### Study description

There have been reports on a potential association between use of doxycycline and suicide. By means of a self-controlled case series and an active comparator cohort study, the study aims to assess the association between use of doxycycline and specific outcomes of interest (i.e. suicidality events). Research questions

- 1. Is there an association between the use of doxycycline and suicide-related events?
- 2. Does the association between doxycycline use and completed suicide and suicide-related events vary by indication of use, compared to active comparators?

Objectives

- 1. To use a new-user cohort study to assess the association between doxycycline and completed suicide, composite suicide and suicide-related events (completed suicide, suicide ideation and suicide attempt, self-harm), composite suicide-related events (suicide ideation, suicide attempt, self-harm), depression and anxiety, compared to active comparators, stratified by indication of acne vulgaris, rosacea, chlamydia and lower respiratory tract infection (CAP or bronchitis)
- 2. To use a self-controlled case series study to assess the association between use of doxycycline and composite suicide-related events (including suicide ideation, suicide attempt, self-harm), depression and anxiety.

Research methods

Study design

New-user cohort study with active comparator (objective 1) and self-controlled case series (objective 2)

Population

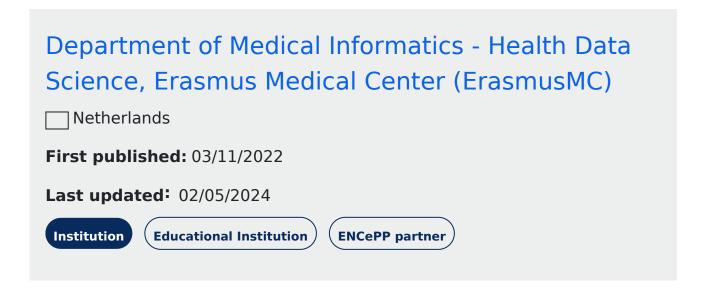
The study population is new users of doxycycline (SCCS and cohort study) or the comparators (cohort). The new-user cohorts will be per indication: acne vulgaris: doxycycline, erythromycin or isotretinoin; rosacea: doxycycline, erythromycin or isotretinoin; chlamydia: doxycycline, azithromycin, erythromycin or amoxicillin; and lower respiratory tract infection (CAP and bronchitis): doxycycline, azithromycin, or amoxicillin.

#### **Study status**

Finalised

## Research institutions and networks

## **Institutions**



## Contact details

## **Study institution contact**

Ilse Schuemie study@darwin-eu.org

Study contact

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**Primary lead investigator** 

### Katia Verhamme

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 16/05/2024 Actual: 16/05/2024

#### Study start date

Planned: 24/07/2024 Actual: 24/07/2024

#### Date of final study report

Planned: 15/08/2024 Actual: 11/11/2024

# Sources of funding

EMA

# Study protocol

DARWIN EU\_D2.2.3\_Protocol\_P3-C3-003\_Suicidality exposure doxycycline\_V4.pdf(863.74 KB)

# Regulatory

| Yes   |
|---|
| Is the study required by a Risk Management Plan (RMP)?  Not applicable  |
| Methodological aspects  |
| Study type  |
| Study type list   |
| Study topic: Human medicinal product  |
| Study type: Non-interventional study  |
| Scope of the study: Disease epidemiology  |
| Data collection methods: Secondary use of data  |
| Study design:  New-user cohort study with active comparator (objective 1) and self-controlled case series (objective 2) |

Was the study required by a regulatory body?

Main study objective:

- 1. To use a new-user cohort study to assess the association between doxycycline and completed suicide, composite suicide and suicide-related events (completed suicide, suicide ideation and suicide attempt, self-harm), composite suicide-related events (suicide ideation, suicide attempt, self-harm), depression and anxiety, compared to active comparators, stratified by indication of acne vulgaris, rosacea, chlamydia and lower respiratory tract infection (CAP or bronchitis)
- 2. To use a self-controlled case series study to assess the association between use of doxycycline and composite suicide-related events (including suicide ideation, suicide attempt, self-harm), depression and anxiety.

# Study Design

#### Non-interventional study design

Case-control

Cohort

# Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**DOXYCYCLINE

#### **Anatomical Therapeutic Chemical (ATC) code**

(J01AA02) doxycycline doxycycline

#### Medical condition to be studied

Suicidal behaviour Suicidal ideation Suicide attempt

Suicide threat

Completed suicide

Depression suicidal

Depression

Anxiety

## Population studied

#### Short description of the study population

The study population is new users of doxycycline (SCCS and cohort study) or the comparators (cohort). The new-user cohorts will be per indication: acne vulgaris: doxycycline, erythromycin or isotretinoin; rosacea: doxycycline, erythromycin or isotretinoin; chlamydia: doxycycline, azithromycin, erythromycin or amoxicillin; and lower respiratory tract infection (CAP and bronchitis): doxycycline, azithromycin, or amoxicillin.

## **Documents**

#### **Study report**

DARWIN EU\_Report\_P3-C3-003\_Doxycycline\_suicidality\_V5.pdf(6.9 MB)

## 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

## Data sources

#### Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

# Use of a Common Data Model (CDM)

#### **CDM** mapping

Yes

#### **CDM Mappings**

#### **CDM** name

**OMOP** 

#### **CDM** website

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

# Data quality specifications

#### **Check conformance**

Unknown

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

Unknown