DARWIN EU® - Suicidality following exposure to doxycycline

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Administrative details

EU PAS number	
EUPAS1000000280	
Study ID	
1000000280	
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

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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

Was the study required by a regulatory body?

Is the study required by a Risk Management Plan (RMP	1P)?
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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)

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 nameDOXYCYCLINE

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