DARWIN EU® - Suicidality following exposure to doxycycline

First published: 25/07/2024

Last updated: 30/01/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000280

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 institution 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

Contact details

Study institution contact

Ilse Schuemie

Study contact

study@darwin-eu.org

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?

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)

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

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