DARWIN EU® - Suicidality following exposure to doxycycline

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Study | Ongoing

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
Ongoing

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
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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

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 data collection

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

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.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink (CPRD) GOLD
Integrated Primary Care Information
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