

DARWIN EU® - Incidence of suicidality in patients with specific chronic skin conditions

First published: 13/08/2024

Last updated: 10/12/2024

Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000294>

EU PAS number

EUPAS1000000294

Study ID

1000000294

DARWIN EU® study

Yes

Study countries

Croatia

Netherlands

Spain

United Kingdom

Study description

Chronic skin conditions like acne and psoriasis cause significant physical and psychological distress, leading to social stigmatization and an increased risk of mental health issues, including depression and anxiety. Concerns about their link to suicidality-related events are rising. Several signals of suicidal ideation associated with treatments for acne and/or other skin disorders have been discussed. For these signals, it is difficult to estimate the extent of the confounding by indication as the underlying patient population is widely believed to be at increased risk of suicide related conditions. Despite this, there is insufficient data in the literature regarding the background rates of such outcomes in these populations and most studies focusing on broader mental health outcomes. This study aims to evaluate suicide-related drug safety signals associated with treatments for the conditions of acne and psoriasis. Understanding of the background rate of suicidality in patients with these conditions and the extent to which this differs from the general population will aid in the assessment of such signals.

Research questions

What are the background incidence rates of suicidality-related events (completed suicide, attempted suicide, suicidal ideation, and intentional self-harm) in patients with acne and psoriasis and in the general population, overall and stratified by sex, age categories, and by calendar year? Results will further be stratified in individuals with and individuals without a medical history of mental health disorders at start of follow-up.

Outcomes of interest are i) completed suicide, ii) attempted suicide, iii) suicide ideation or iv) intentional self-harm, v) suicide-related events (i.e. completed

suicide, attempted suicide, and suicidal ideation), vi) composite outcomes (combination of all above mentioned events).

Study status

Finalised

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
- Hungary
- Netherlands
- Norway
- Portugal
- Spain
- United Kingdom

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2024

Actual: 01/07/2024

Study start date

Planned: 25/07/2024

Actual: 25/07/2024

Date of final study report

Planned: 20/12/2024

Actual: 26/11/2024

Sources of funding

- EMA

Study protocol

[DARWIN EU_Protocol_P3-C1-010_Suicidality and skin conditions_V3.pdf\(842.83 KB\)](#)

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 topic:

Disease /health condition

Study topic, other:

Chronic skin conditions

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Population level cohort study

Main study objective:

1. To assess the incidence rate of i) completed suicide, ii) attempted suicide, iii) suicide ideation, iv) intentional self-harm, v) suicide-related events (i.e. completed suicide, attempted suicide, and suicidal ideation), vi) composite outcomes (combination of all above mentioned events) in patients with acne stratified by sex, age category (12-<18 years, 18-30, 31-40, 41-50 etc, >=81 years), calendar year, and history of mental health disorders.
2. To assess the incidence rate of i) completed suicide, ii) attempted suicide, iii) suicide ideation, iv) intentional self-harm, v) suicide-related events (i.e. completed suicide, attempted suicide, and suicidal ideation), vi) composite outcomes (combination of all above mentioned events) before in patients with psoriasis stratified by sex, age category (12-<18 years, 18-30, 31-40, 41-50 etc, >=81 years), calendar year, and history of mental health disorders

3. To assess the incidence rate of i) completed suicide, ii) attempted suicide, iii) suicide ideation, iv) intentional self-harm, v) suicide-related events (i.e. completed suicide, attempted suicide, and suicidal ideation), vi) composite outcomes (combination of all above mentioned events) before in the general population stratified by sex, age category (12-<18 years, 18-30, 31-40, 41-50 etc, >=81 years), calendar year, and history of mental health disorders

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acne

Psoriasis

Population studied

Short description of the study population

The study population will include all individuals present in the database during the study period (2010 to the most recent data available) and with at least one year of database history.

Within this population 2 sub-cohorts will be nested namely one on individuals newly diagnosed with acne and one consisting of individuals newly diagnosed with psoriasis.

Study design details

Setting

This study will be conducted using routinely collected data from 5 primary and secondary care data sources in 5 European countries. All data were a priori mapped to the OMOP CDM.

Outcomes

Outcomes of interest are i) completed suicide, ii) attempted suicide, iii) suicide ideation or iv) intentional self-harm, v) suicide-related events (i.e. completed suicide, attempted suicide, and suicidal ideation), vi) composite outcomes (combination of all above mentioned events).

Documents

Study report

[DARWIN EU_Report_P3-C1-010_Skin conditions and suicidality_V3.pdf](#)(3.44 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)

The Valencia Health System Integrated Database

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/>

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown