DARWIN EU® - Characterisation of exposure to acitretin and purpura and related conditions

First published: 04/01/2025

Last updated: 29/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000429

EU PAS number

EUPAS1000000429

Study ID

1000000429

DARWIN EU® study

Yes

Study countries

☐ Denmark

☐ Netherlands

☐ Spain

☐ United Kingdom

Study description

The Marketing Authorisation Holders (MAHs) that hold Marketing Authorisations (MAs) for acitretin in Canada and the US have included purpura in their label. The Pharmacovigilance Risk Assessment Committee (PRAC) requested additional real-world evidence (RWE) to assess the causal association between certain purpura and related conditions and acitretin before deciding whether to include selected purpura and related conditions in section 4.4 (or 4.8) of the Summary of product characteristics (SmPC) of acitretin.

Acitretin (D05BB02) is a synthetic aromatic analogue of retinoic acid. Retinol (a derivative of Vitamin A) is known to be essential for normal epithelial growth and differentiation. Acitretin is a Nationally Authorised Product (NAP) with approved indications including severe forms of psoriasis (erythrodermic psoriasis and local or generalized pustular psoriasis); severe disorders of keratinization such as congenital ichthyosis, pityriasis rubra pilaris, and Darier’s disease. And other disorders of keratinization which may be resistant to other therapies. It is authorised in the majority of EU countries (not in Bulgaria, Cyprus, Greece, Malta, Romania).

This study aims to characterise patients treated with acitretin, estimate the incidence rate of purpura and related conditions in patients with treatment indications for acitretin.

Study status

Ongoing

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

Last updated: 11/06/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cheryl Tan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2024

Actual: 31/07/2024

Study start date

Planned: 12/12/2024

Actual: 12/12/2024

Date of final study report

Planned: 30/04/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-021_Acitretin and purpura_V2.pdf(921.97 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:

Drug utilisation

Study design:

• New drug user cohort (Objectives 1-2)

• Population-level descriptive epidemiology (Objective 3)

Main study objective:

1. To characterise patients initiating treatment of acitretin in terms of:

a. Demographics

b. Treatment indications

c. Risk factors for purpura and related conditions

d. Comorbidities

2. To describe patient-level acitretin utilisation in a cohort of new users including:

a. Duration of treatment

b. Concomitant medications prescribed at/before/after index date

3. To estimate crude and age-sex standardised incidence rates of purpura and related conditions (and stratified by thrombocytopenic purpura vs non-thrombocytopenic purpura) in patients with common indications for acitretin and/or treatment groups, namely:

a. Treatment: methotrexate, cyclosporine, azathioprine-containing immunosuppressants; acitretin; TNF alpha inhibitors; interleukin inhibitors

b. Indication (psoriasis vs other)

c. Treatment-indication combination: Acitretin-psoriasis, Acitretin-keratinization,

Acitretin-unknown/other, Methotrexate-psoriasis, Azathioprine/cyclosporine immunosuppressants-psoriasis, TNF alpha inhibitors-psoriasis, Interleukin inhibitors-psoriasis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ACITRETIN

Anatomical Therapeutic Chemical (ATC) code

(D05BB02) acitretin

acitretin

Medical condition to be studied

Purpura

Population studied

Short description of the study population

Patient-level characterisations (Objectives 1-2): New users of acitretin in the study period between 01/01/2010 and 31/12/2023 (or the latest date of data availability of the respective databases), with at least 365 days of visibility prior to the date of their first prescription and no prior use of acitretin.

Population-level descriptive epidemiology (Objective 3): New users of acitretin, alternative treatments, and/or diagnosis of a condition of interest in the study period between 01/01/2010 and 31/12/2023 (or the latest date of data availability of the respective databases), with at least 365 days of visibility prior to the date of their first prescription and no prior use of the respective drug/s, will comprise the denominator population based on the respective treatment and indication groups.

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Danish Health Data Registries

Clinical Practice Research Datalink (CPRD) GOLD

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown