

# Evaluation of the effectiveness of pregnancy prevention programme (PPP) for oral retinoids (acitretin, alitretinoin, and isotretinoin): a European before-after drug utilization study (DUS) using secondary data

**First published:** 18/11/2019

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32302

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### Study ID

50574

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### DARWIN EU® study

No

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### Study countries

- ☐ France
  - ☐ Germany
  - ☐ Spain
  - ☐ Sweden
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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Real World Solutions, IQVIA

- ☐ Netherlands
- ☐ United Kingdom (Northern Ireland)

**First published:** 28/04/2011

**Last updated:** 22/03/2024

**Institution**

Other

ENCePP partner

## Contact details

### Study institution contact

Ehlken Birgit PAS\_registrations@iqvia.com

**Study contact**

[PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

## Primary lead investigator

Ehlken Birgit

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/06/2018

Actual: 30/11/2018

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### Study start date

Planned: 01/07/2021

Actual: 08/10/2021

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### Data analysis start date

Planned: 03/01/2022

Actual: 04/02/2022

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### Date of final study report

Planned: 31/12/2022

Actual: 02/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Oral Retinoids Consortium consisting of 34 Marketing Authorisation Holders

# Study protocol

[Oral Retinoids PASS DUS protocol v3.0 Redacted\\_No Annex.pdf](#)(1.13 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

## **Data collection methods:**

Secondary use of data

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## **Main study objective:**

The main objective of the study is to assess if there is a difference in physicians' prescribing and monitoring practice in the periods before and after the update of the pregnancy prevention programme (PPP) for the oral retinoids acitretin, alitretinoin, and isotretinoin when treating women of childbearing potential?

# Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Multicountry, multisource, observational study

# Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(D05BB02) acitretin

acitretin

(D10BA01) isotretinoin

isotretinoin

(D11AH04) alitretinoin

alitretinoin

# Population studied

## **Short description of the study population**

The study population included females of childbearing potential aged 13-49 years old received treatment with oral retinoids (i.e., acitretin, alitretinoin and isotretinoin) identified through the selected data sources in the targeted European countries (i.e., France, Germany, Spain, and Sweden).

Inclusion criteria:

- Female gender
- Childbearing potential (13-49 years of age, inclusive)
- Received or prescribed at least one prescription of the oral retinoids acitretin, alitretinoin, or isotretinoin in either the pre-implementation or post-implementation period

Exclusion criteria:

- All females in the age group 13 to 49 years with available information that they are not of childbearing potential before initiation of oral retinoids (such as records of hysterectomy or sterilisation) will be excluded.
  - Data for the oral retinoids acitretin, alitretinoin, and isotretinoin will only be extracted from databases in target countries where the respective active substance has been granted market authorisation.
  - No further exclusion criteria will be applied.
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## **Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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## **Special population of interest**

Pregnant women

Women of childbearing potential using contraception

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## **Estimated number of subjects**

150000

# Study design details

## **Outcomes**

To evaluate the changes in the prescribing and monitoring practices following the update of the PPP in females of childbearing potential receiving prescriptions of the oral retinoids acitretin, alitretinoin, or isotretinoin by comparing contraceptive use, prescription interval, and laboratory pregnancy tests in the period before and after the implementation of the updated PPP, The secondary outcome of the study is to described the patient profile, the prescriber profile, the exposure characteristics, incidence of pregnancies during oral retinoid exposure, trends in the physician's prescribing and monitoring practice, and assess the elements of the primary outcomes by active substance.

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## **Data analysis plan**

The data extracted from the data sources will be analysed by country and by active substance for the elements of the primary outcomes. The analysis will descriptively analyse the prescribing and monitoring patterns in females of childbearing potential treated with oral retinoids before and after the implementation of the updated pregnancy prevention programme. The secondary outcomes will be analysed descriptively as well. To assess the trends in the prescribing and monitoring practice of oral treatment, an interrupted time series analysis will be performed.

# Documents

## **Study results**

## 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 but are no longer maintained.

## Data sources

### Data source(s)

The Information System for Research in Primary Care (SIDIAP)  
Sweden National Prescribed Drugs Register / Läkemedelsregistret

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### Data source(s), other

Système National d'Information Inter-Régimes de l'Assurance Maladie (SNIIRAM)  
France, Company Health Insurance funds Germany, Swedish national patient register Sweden, Swedish national birth register Sweden

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)



**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No