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

Study ID

50574

DARWIN EU® study

No

Study countries

France

Germany

Spain

Sweden

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

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Study contact

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Primary lead investigator

Ehlken Birgit

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2018

Actual: 30/11/2018

Study start date
Planned: 01/07/2021

Actual: 08/10/2021

Data analysis start date
Planned: 03/01/2022

Actual: 04/02/2022

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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

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.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Women of childbearing potential using contraception

Estimated number of subjects

150.000

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 preganancy 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.

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

32302_20221202_OR DUS_FinalReport_V1.0_Abstract.pdf (292.66 KB)

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

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No