Patient and Prescriber Survey: Effectiveness measures to investigate awareness, knowledge and adherence to the Risk Minimisation Measures (RMMs) of the Pregnancy Prevention Program (PPP) for Oral Retinoids (Acitretin, Alitretinoin, and Isotretinoin)

First published: 16/11/2020

Last updated: 28/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38096

Study ID

50298

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Norway
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom

Study description

This survey aims to assess the effectiveness of the updated risk minimisation measures (RMMs) among female oral retinoid patients who are of childbearing potential and their prescribers and to assess patients' and prescribers' (HCPs') awareness and knowledge of and adherence to the pregnancy prevention programme (PPP). Primary objective: to assess the effectiveness of the PPP based on pre-defined success thresholds for PPP awareness, knowledge, and adherence in HCPs and patients. Secondary objectives: (1) to assess HCPs' and patients' awareness of the updated PPP (2) to assess HCPs' and patients' knowledge of the risks and RMMs associated with the use of oral retinoids (3) to assess whether HCPs and patients adhere to the RMMs of the updated PPP

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

Birgit Ehlken

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2018

Actual: 30/11/2018

Study start date

Planned: 31/03/2021

Actual: 24/03/2021

Data analysis start date
Planned: 01/10/2021

Actual: 07/10/2021

Date of final study report
Planned: 31/03/2022

Actual: 15/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

A Consortium of Marketing Authorization Holders for oral retinoids

Study protocol

20200727_Oral Retinoids_PASS_Survey_Protocol_v5.0_Redacted_NO ANNEX.pdf
(2.71 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primary objective: to assess the effectiveness of the PPP based on pre-defined success thresholds for PPP awareness, knowledge, and adherence in HCPs and patients

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Multinational, multi-channel survey

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

A survey of healthcare professionals prescribed or administered oral retinoids (acitretin, alitretinoin and isotretinoin) to female patients of childbearing potential according to the local label in seven European countries.

Inclusion criteria:

HCPs

· HCPs who prescribed or administered oral retinoids (acitretin, alitretinoin and isotretinoin) to female patients of childbearing potential in the past 6 months

Patients

· Female gender

· Childbearing age (i.e., 13 to 49 years of age)

· Receiving prescriptions for oral retinoids (acitretin, isotretinoin or alitretinoin) at the time of the survey, or who have received prescriptions within the last 6 months

· Willing, understanding and consenting to participate in this self-administered survey. For patients between 13 to 17 years of age, the survey shall be filled out by their parent, guardian or caregiver.

Exclusion criteria

HCPs

· Inactive and retired HCPs (when documented information is available to identify them) will be deleted from the contact lists before randomization.

· HCPs who are not involved in patient treatment (e.g. researchers)

· HCPs who may have conflicts of interest with the survey (i.e., HCPs employed by regulatory bodies, pharmaceutical companies)

· HCPs who belong to a practice from which there are already at least two other HCPs participating in the survey

· HCPs who have participated in testing the questionnaire for comprehensibility, consistency and the appropriateness of medical terms

Patients

· Patients who may have conflicts of interest with the survey (i.e. patients employed by regulatory bodies, pharmaceutical companies)

· Patients who have a condition that prevents them from becoming pregnant and having children

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Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

600

Study design details

Data analysis plan

Results will be presented, overall and at country level stratified by HCP speciality and per molecule. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, first quantile (Q1), third quantile (Q3), minimum, and maximum. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals (CIs) of 95% will be calculated when relevant. Individual awareness, knowledge and adherence scores will be calculated as the percentage of correctly answered survey questions. Overall domain level scores will be calculated as the mean of individual scores. Calculations will first be performed on raw data, which will be stratified by speciality for the HCP survey, and weighted according to the real proportion of targeted responders for both the HCP and patient surveys per country to accurately reflect the population the survey seeks to measure.

Documents

Study results

38096_20220215 Oral Retinoids_PASS_Survey_Final Report_v1.0_Abstract.pdf (228.94 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 sources (types)

Other

Data sources (types), other

The recruitment of HCPs will be conducted using the OneKey database, which provides the lists and contact details of healthcare providers. Patients will be recruited by HCPs from OneKey.

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