# Impact of EU label changes and revised pregnancy prevention programme for oral retinoid containing medicinal products: risk awareness and adherence (RetinoidRiskAware)

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# Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/49658

#### **EU PAS number**

**EUPAS32408** 

#### Study ID

49658

#### **DARWIN EU® study**

No

#### **Study countries**

Belgium

Denmark

Greece

Latvia

Netherlands

**Portugal** 

Slovenia

Spain

### Study description

This is a multi-country study in eight European countries: Belgium, Denmark, Greece, Latvia, Portugal, The Netherlands, Slovenia and Spain. In each country a web-based questionnaire will be conducted among users and former users of oral retinoids, and among health care professionals. An electronic survey including questions on the influence of regulatory recommendations on HCP awareness about the teratogenic and neurodevelopment effects of oral retinoids will be used to gauge their perspective and to assess effects on knowledge, attitudes and practices. Similary a patient questionnaire will measure awareness about regulatory recommendations as well as uptake of pregnancy prevention measures, and investigate their effect on oral retinoid use. Data from the survey and questionnaire will be anonymised and analysed for differences between countries. Determinants for adherence to the measures implemented per country will be analysed. Additionally, in two countries (Netherlands and Portugal) semi-structured telephone interviews will be held with 6-8 patients with a range in age and varied educational background.

## Study status

Finalised

# Research institution and networks

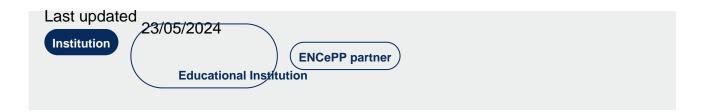
# Institutions



Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

First published: 01/03/2010



# Porto Pharmacovigilance Centre, Faculty of Medicine, University of Porto (UFPorto)

Portugal
First published: 17/11/2010
Last updated
Institution

ENCePP partner
Educational Institution

# Department of Medicine/Laboratory of Hygiene and Environmental Protection, Democritus University of Thrace



Pharmaceutical Care Unit – Ghent University Ghent, Belgium, University of Copenhagen, Faculty of Health and Medical Sciences, Department of Pharmacy (Social and Clinical Pharmacy). Copenhagen, Denmark, The Institute of Public Health of Riga Stradins University Riga, Latvia, University of Ljubljana, Faculty of pharmacy, Social Pharmacy. Ljubljana, Slovenia, Sección de Innovación y Organización, Servicio Navarro de Salud. Pamplona, Spain, Centre for Health Protection, National

# Institute for Public Health and the Environment Bilthoven, The Netherlands

# **Networks**

Pharmacoepidemiology and Pharmacovigilance Network First published: 01/02/2024

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Network

# Contact details

Study institution contact Teresa Leonardo Alves

**Study contact** 

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Primary lead investigator

Olaf Klungel

Primary lead investigator

# Study timelines

Date when funding contract was signed

Planned: 25/02/2019 Actual: 25/02/2019

Study start date

Planned: 25/10/2019 Actual: 25/10/2019

Data analysis start date

Planned:

# Date of interim report, if expected

Planned: 24/07/2020

## **Date of final study report**

Planned: 23/08/2019 Actual: 01/04/2021

# Sources of funding

EMA

# Study protocol

29-01-2020 Protocol retinoid study version 2.0 final with annexes.pdf(594.87 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 list

Study topic:

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Drug utilisation Effectiveness study (incl. comparative)

#### Data collection methods:

Primary data collection

# Main study objective:

To determine the extent of awareness of the PPP and of the risk of teratogenic effects in women of childbearing potential and pregnant women exposed to oral retinoid containing medicinal products, by patients and by healthcare professionals.

# Study Design

#### Non-interventional study design

Cross-sectional Other

#### Non-interventional study design, other

Health care professional study, Patient study

# Study drug and medical condition

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

(D05BB02) acitretin (D10BA01) isotretinoin (D11AH04) alitretinoin

# Population studied

#### Short description of the study population

Health care professionals (both GPs and specialists) and community pharmacists who had prescribed oral retinoids among women in childbearing age from 8 European countries: Belgium, Denmark, Greece, Latvia, Portugal, The Netherlands, Slovenia and Spain. Midwives may be included, if they have had experience with at least one woman treated

with oral retinoids.

Inclusion criteria:

- female aged between 15-50 years
- having used oral retinoids in the past 5 years or are currently using

#### Age groups

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

#### Special population of interest

Women of childbearing potential not using contraception Women of childbearing potential using contraception

# **Estimated number of subjects**

400

# Study design details

### Data analysis plan

The surveys will generate descriptive statistics, describing the distribution of characteristics of patients and HCPs for the variables included in the querstionnaires. Univariate and bivariate analyses will be conducted according to stratifying variables, including HCP characteristics (age, gender, country, specialism, years of experience) and patient characteristics (age, diagnosis, past use of oral retinoids, type of prescriber, country). For the qualitative data, the analysis involves an inductive content analysis based on a close line-by-line reading of the responses and developing a conceptual coding scheme based on the major themes in the interview guides. Transcripts will be categorized individually by two coders in each country in native languages. Coders from all countries will meet prior to the analysis to predefine categories and codes to be used. They meet again to evaluate the categories identified and to write up the results using illustrative quotes.

# **Documents**

# Study results

RetinoidRiskAware Summary.pdf(165.7 KB)

#### Study report

RetinoidRiskAware study report\_revised\_final.pdf(1.62 MB)

# Data management

# **Data sources**

# Data sources (types)

Administrative data (e.g. claims) Drug dispensing/prescription data Other

# Data sources (types), other

Prospective patient-based data collection, For recruitment> Patient Organizations and their networks Social Media

# 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