Retinoid-containing medicinal products and Neuropsychiatric disorders: A descriptive analysis of EudraVigilance data

First published: 20/01/2021

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36901

Study ID

36902

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A cross-sectional descriptive study of case reports of Neuropsychiatric disorders to Retinoid-containing medicinal products was conducted. Case reports were extracted from EudraVigilance, from inception to 19 July 2016 where single or multi-ingredient formulations of Acitretin, Adapalene, Alitretinoin, Bexarotene, Isotretinoin, Tretinoin, Tazarotene were reported as suspect or interacting medicinal products and there was at least one Preferred Term of the Psychiatric disorders SOC.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pinheiro Luis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/09/2016

Actual: 06/09/2016

Study start date

Planned: 06/09/2016

Actual: 06/09/2016

Data analysis start date

Planned: 31/08/2016

Actual: 31/08/2016

Date of interim report, if expected

Planned: 21/09/2016

Actual: 21/09/2016

Date of final study report

Planned: 23/09/2016

Actual: 27/09/2016

Sources of funding

- EMA

Study protocol

Retinoids Art 31 Data Analysis synopsis - 20160905.pdf (109.66 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

EMEA/H/A-31/1446

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Description of case series

Data collection methods:

Secondary use of data

Main study objective:

To provide a comprehensive overview of the case reports of neuropsychiatric adverse events associated with the use of retinoid-containing medicinal products.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

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

ACITRETIN

ADAPALENE

ALITRETINOIN

BEXAROTENE

ISOTRETINOIN

TRETINOIN

TAZAROTENE

Medical condition to be studied

Depression

Suicidal ideation

Anxiety

Additional medical condition(s)

Psychiatric disorders System Organ Class

Population studied

Short description of the study population

All case of neuropsychiatric disorders reported to any retinoidcontaining medicinal product from inception up to July 2016.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Estimated number of subjects

10295

Study design details

Data analysis plan

Summary tabulations were produced for the distribution of reports per retinoid, route of administration, reporting year (receive date), location (country), demographic characteristics (age groups, gender), medical history (history of psychiatric disorders) and duration of treatment. Where possible, correlations of the abovementioned variables were provided. To report on relevant MedDRA PTs, Proportional reporting ratios were used as a disproportionality metric and were calculated for each INN and MedDRA PT. This data was analysed cumulatively for all retinoids, stratified by individual retinoid and stratified by route of administration. Output tables were adjusted accordingly. The analysis pertaining to fatal cases resulting from self-injury was presented separately as a subgroup analysis.

Documents

Study results

Retinoid Art 31 referral - EV analysis of neuropsychiatric reactions.pdf (592.05 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), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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