Monitoring of the Lenalidomide Pregnancy Prevention Programme (PPP) Implementation and Effectiveness in Europe (Lena-PIE Europe)

First published: 25/10/2022

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49558

EU PAS number

EUPAS49520

Study ID

49558

DARWIN EU® study

No

Study countries

Germany

Study description

Evaluation of the outcome indicator (safety outcome): (i) Systematic database review in STADA’s safety database to ensure that no pregnancy case in association with an exposition to a lenalidomide product of the STADA group included in the concerned procedures was missed. Initiation of follow-up and root-cause analysis of missed cases. (ii) Systematic review of EudraVigilance data to identify pregnancy cases in association with an exposition to a lenalidomide product of the STADA group included in the concerned procedures not known to STADA. Initiation of data entry and processing in STADA’s safety database as well as initiation of follow-up and root-cause analysis of cases not known.

Study status

Ongoing

Research institutions and networks

Institutions

STADA Arzneimittel

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Markus Torben Schweimer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/10/2022

Actual: 05/10/2022

Study start date

Planned: 27/10/2022

Actual: 27/10/2022

Data analysis start date

Planned: 27/10/2027

Date of final study report

Planned: 27/10/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STADA Arzneimittel AG

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)

Other study registration identification numbers and links

STADA study code: PASS-37480-22-0250

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Main study objective:

The objectives of this study are to perform a cumulative root-cause analysis for all pregnancies which have occurred in association with an exposition to a lenalidomide product of the STADA group included in the concerned procedures (IS/H/0275/001-007/DC, IS/H/0376/001-007/DC, IS/H/0377/001-007/DC) and to identify causes that could indicate a failure or weakness of the PPP.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AX04) lenalidomide

lenalidomide

Medical condition to be studied

Exposure during pregnancy

Population studied

Age groups

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)

Special population of interest

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

Pregnancy in female patient: conception up to 4 weeks after lenalidomide exposition in female patient // Pregnancy in female partner of male patient: conception up to 7 days after lenalidomide exposition in male patient

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Data analysis plan

Data analysis is performed as follows: (i) Cumulative case analysis of all pregnancy cases in association with an exposition to a lenalidomide product of the STADA group included in the concerned procedures, (ii) Descriptive statistics for summarizing data from pregnancy cases in association with an exposition to a lenalidomide product of the STADA group included in the concerned procedures

Data management

Data sources

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Systematic database review

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