Study to Evaluate Physician Awareness and Knowledge of Safety and Safe Use Information for Androcur and Other Cyproterone Acetate Monotherapies in Europe: an Observational Post-Authorisation Joint Safety Study (Safe-CAM)

First published: 11/06/2021

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS41194

Study ID

50248

DARWIN EU® study

No

Study countries

France
Germany
Netherlands
Poland
Spain

Study description

Androcur is a type of treatment called cyproterone acetate (CPA). Androcur and other CPA treatments work by blocking a group of male sex hormones called androgens in the body. It can be given to men and women to treat conditions that are caused by higher levels of androgens. CPAs, including androcur, are currently available as treatments for doctors to give to patients who have these types of conditions. But, in a study, researchers found that participants had a certain medical problem when they took CPAs for a long time. This medical problem was a tumor of the brain or spinal cord that is mostly not malignant and is called meningioma. This eventually led health authorities to change the instructions for how doctors should use CPAs to treat patients. This included what health conditions should be treated with CPAs, how long patients should receive them, and what dose of CPA should be given. In this study, the researchers want to learn more about how doctors are using CPAs to treat patients after the update to the instructions. To answer this research question, they will give to the doctors a web-based questionnaire asking about the advisability or necessity of the treatment (also called “indications of approved use”), the measures to be followed to reduce the risk and how much the doctors knew about the risk of meningioma. The researches will then analyze the answers to the questionnaire. The results will be the percentage of physicians with correct answers for each individual knowledge question from the questionnaire. The study will include information collected from a diverse sample of doctors during approximately 3 months. The doctors must have given CPAs as a treatment to at least 1 patient in the last 12 months. There are no

required visits or tests in this study.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials Contact BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/02/2021

Actual: 18/02/2021

Study start date
Planned: 20/10/2021

Actual: 18/10/2021

Date of final study report
Planned: 01/07/2022

Actual: 05/05/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21490_Safe-CAM_Protocol_v2.0_18Feb2021_Redacted.pdf (541.34 KB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to measure physician awareness and level of knowledge of the key safety information included in the revised summary of product characteristics (SmPC) and the Direct Healthcare Professional Communication (DHPC) for CPA monotherapy regarding the risk of meningioma.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Observational survey

Study drug and medical condition

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

CYPROTERONE ACETATE

Medical condition to be studied

Virilism

Prostate cancer

Antiandrogen therapy

Population studied

Short description of the study population

A survey of physicians, including dermatologists, endocrinologists, gynaecologists, general practitioners, urologists, oncologists, and psychiatrists, involved in treating hypersexuality and reducing drive in sexual deviations, who have prescribed cyproterone acetate (CPA) in the past 12 months and work in office or hospital-based settings, is being conducted in France, Germany, Poland, Spain, and the Netherlands.

Inclusion criteria:

1. Licensed and practising dermatologist, endocrinologist, gynaecologist,

general practitioners, urologist, oncologist (who treats prostate cancer), or psychiatrist involved in the treatment of hypersexuality/reduction of drive in sexual deviations
2. Prescribed CPA monotherapy to at least one patient in the past 12 months
3. Work in an office or hospital-based setting
4. Electronic acknowledgement of informed consent

Age groups

- 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

600

Study design details

Outcomes

Percentage of physicians responding correctly to the knowledge questions. For more details, please visit www.clinicaltrials.gov and search using the study number 21490.

Data analysis plan

All analyses will be descriptive in nature, and no hypothesis testing will be performed. The frequency distribution of responses to each individual question will be calculated.

Documents

Study results

21490_EU PAS Abstract_Redacted_V1.0_2022-06-23.pdf (220.53 KB)

Study report

21490_EU PAS Report_Redacted_V1.0_2022-06-23.pdf (1.62 MB)

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

Physician survey

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