Depression following exposure to anastrozole

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39771

EU PAS number

EUPAS39770

Study ID

39771

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Anastrozole is drug that is widely used for the treatment of certain types of breast cancer in older women. Recently, its use has been reported as being associated with the onset of depressive illness. This issue is being evaluated by the European Union’s Pharmacovigilance Risk Assessment Committee (PRAC), which is a regulatory body responsible for assessing and monitoring the safety of human medicines. This study simply describes how often depressive illness occurs after patients are prescribed anastrozole and shows how this varies with time. To allow contextualisation of the results, the same analysis has also been done in two other groups of patients. The first group are patients prescribed a similar medicine also used in the treatment of breast cancer (tamoxifen). The second group are patients who have had breast cancer and are then prescribed a medicine which is not used for the treatment of breast cancer and which is not known to cause depression (bendroflumethiazide). The results of this study will be used by the PRAC in its decision-making process by helping to decide if regulatory action needs to be taken to protect patients taking anastrozole in the future.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/09/2020

Actual: 01/09/2020

Study start date

Planned: 01/09/2020

Actual: 01/09/2020

Date of final study report

Planned: 08/12/2020

Actual: 08/12/2020

Sources of funding

- EMA

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

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Is there an association between exposure to anastrozole and subsequent risk of depressive illness?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ANASTROZOLE

Medical condition to be studied

Depression

Population studied

Short description of the study population

The population eligible for the study consisted of all female patients registered with an IMRD-UK for a duration of one-year or more. Patients were followed from the latest of date of registration, Acceptable Mortality Reporting (AMR) date or date of practice computerisation, and followed until the earliest of

transfer out date, date of death or date of last data collection (the most recent data being available for January 2020). The study subjects were followed from the first use of anastrozole (or tamoxifen or bendroflumethiazide) to the end of follow-up on the database or until first use of the other drug (tamoxifen or anastrozole). To ensure that cases of depression were of new onset and were not associated with the comparator drug, the following were excluded:
• patients with less than 1-year lookback prior to first prescribing of anastrozole or tamoxifen or bendroflumethiazide (e.g. negative controls)
• negative control patient prescribed bendroflumethiazide prior to diagnosis of breast cancer
• patients with a history of treatment for depression or diagnosis of depression in the year prior to first use of the drug
• patients exposed to tamoxifen prior to their first use of anastrozole (i.e. prevalent users of tamoxifen to be excluded)
• patients exposed to anastrozole prior to their first use of tamoxifen (i.e. prevalent users of anastrozole to be excluded)
• negative control patients exposed to either anastrozole or tamoxifen prior to their first use of bendroflumethiazide (i.e. prevalent users of anastrozole or tamoxifen to be excluded)

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

9644

Study design details

Outcomes

Depression defined as either diagnosed depression or initiation of treatment of depression

Data analysis plan

The event rate of new onset depression was calculated every 30-days as the cumulative number of cases of new onset depression divided by the total duration of follow-up time in years. Patient were censored from the analysis if they left the population (moved practice, died or reached the end of follow-up for their practice) or if they received the other drug (tamoxifen or anastrozole). Analyses were conducted using SAS v9.4.

Documents

Study results

Depression following anastrozole - final report.pdf(326.17 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

Electronic healthcare records (EHR)

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