Use of products containing oestrogens alone and oestrogens in combination with progestogens (not contraceptives) between 2000 and 2014 in France, Germany and the UK

First published: 29/11/2019

Last updated: 29/11/2019

Study Finalised

Administrative details

EU PAS number

EUPAS32500

Study ID

32501

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

United Kingdom

Study description

The objective of the study is to estimate the extent of use and the duration of use of products containing oestrogens alone and oestrogens in combination with progestogens, primarily for HRT, between the years 2000-2014 in several European Union Member States, namely the United Kingdom (UK), France (FR) and Germany (DE). It should be noted that it is not possible to identify these products exclusively in the context of HRT but the ATC codes were selected with this consideration in mind and the age distribution of the women in the study suggests that this strategy is generally successful. The study is not restricted to specific age groups since, although the motivation for the study arises from the findings in women treated with HRT, the exposure of women to the same drugs in the context of other indications is also of interest

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Karin Hedenmalm karin.hedenmalm@ema.europa.eu

Study contact

karin.hedenmalm@ema.europa.eu

Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2015

Actual: 15/05/2015

Study start date

Planned: 15/05/2015

Actual: 15/05/2015

Data analysis start date

Planned: 15/05/2015

Actual: 15/05/2015

Date of final study report

Planned: 07/09/2015

Actual: 07/09/2015

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Drug utilisation study of HRT

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03F) PROGESTOGENS AND ESTROGENS IN COMBINATION

PROGESTOGENS AND ESTROGENS IN COMBINATION

Population studied

Short description of the study population

Women in all age groups with a prescription of a product containing an oestrogen alone or an oestrogen in combination with a progestogen between 1 st January 2000 and 31st December 2014.

For the UK, data were only available for a part of 2014, and hence, yearly prevalences are provided until 31 December 2013.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

200000

Study design details

Data analysis plan

Prevalence and duration of exposure

Documents

Study results

HRT Study results.pdf(1.75 MB)

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