Use of ondansetron in pregnant female patients in the IMS Disease Analyzer databases in France and Germany (Ondansetron use pregnancy)

First published: 24/04/2020

Last updated: 24/04/2020

Study Finalised

Administrative details

EU PAS number

EUPAS34908

Study ID

34909

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

Study description

Pregnancy was identified on the basis of diagnosis codes for pregnancy, and possible time of pregnancy was derived from the pregnancy code and the date when the code was recorded. Use of ondansetron was then identified during the time interval of possible pregnancy.

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: 01/04/2019

Actual: 01/04/2019

Study start date
Planned: 01/04/2019

Actual: 01/04/2019

Data analysis start date
Planned: 01/04/2019

Actual: 01/04/2019

Date of final study report
Planned: 02/05/2019

Actual: 02/05/2019

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This aim was to identify use of ondansetron in women during pregnancy in France and Germany as identified in the IMS Disease Analyzer (DA) databases. Due to concern that ondansetron may be increasingly used for hyperemesis gravidarum a further aim was to study the yearly proportion of women with a diagnosis of excessive vomiting of pregnancy treated with ondansetron between 2005 and 2018.

Study drug and medical condition

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

ONDANSETRON

Medical condition to be studied

Pregnancy

Hyperemesis gravidarum

Population studied

Short description of the study population

All pregnant women with no prior diagnosis of cancer are identified, and all use of ondansetron during pregnancy in women with no prior diagnosis of cancer is captured. Pregnant women with excessive vomiting in pregnancy are then specifically identified, and use of ondansetron in these women is captured.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

100000

Study design details

Data analysis plan

The yearly number of pregnant women was calculated and the number of pregnant women with a prescription for ondansetron during the time of pregnancy was presented. The proportion of women with a diagnosis of hyperemesis gravidarum that had received a prescription for ondansetron was calculated.

Documents

Study, other information

Ondansetron.pdf(807.2 KB)

Data management

Data sources

Data source(s)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

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