Pregnancy Registry for Eurartesim

First published: 27/06/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6929

Study ID

30212

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

A 5 year European multi-centre pregnancy registry for patients exposed to Eurartesim whilst pregnant which aims to assess the live birth incidence of minor and major congenital birth defects following exposure to Eurartesim whilst pregnant. Both mother and child will be followed from enrolment until 12 months after the end of the pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

☐ Germany

☐ Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Multiple centres: 31 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ron Behrens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2011

Actual: 01/11/2011

Study start date

Planned: 01/06/2012

Actual: 03/08/2015

Date of final study report

Planned: 01/01/2019

Actual: 17/04/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sigma-Tau

Study protocol

3351_Sigma Tau_Pregnancy Registry_Protocol_20120626_v12.0_Clean_signed.pdf(632.26 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

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

Data collection methods:

Primary data collection

Main study objective:

To assess the live birth incidence of minor and major congenital birth defects following exposure to Eurartesim whilst pregnant or in the one (1) month (30 days) prior to conception.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A European multi-centre pregnancy Registry for patients exposed to Eurartesim™ whilst pregnant, Active surveillance

Study drug and medical condition

Name of medicine

EURARTESIM

Medical condition to be studied

Malaria

Population studied

Short description of the study population

The following patients were included in the study:

- Women;

- who have received Eurartesim™ for malaria whilst pregnant, within one (1) month (30 days) before or at any time after conception, or

- whose partner (the biological father) has received any formulation of Eurartesim™ for malaria within one (1) month (30 days) prior to conception (Committee for
Medicinal Products for Human Use, 2005), and

- who have been informed and agree to participate in this study

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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

357

Study design details

Outcomes

Estimation of the incidences of birth defects and spontaneous abortion. Frequency and type of pregnancy outcome will be stratified by the earliest trimester of exposure, demographics and medical background characteristics. Pregnancy outcomes will be analysed according to parameters such as lifestyle factors, concomitant medications/infections and medication use.

Data analysis plan

All analysis will be conducted in 2 ways, on all women, and by stratifying the women depending on whether they were directly exposed to Eurartesim or whether the biological father was exposed to Eurartesim.Continuous variables will be described by their mean, SD, median quartiles 1 and 3, extreme values and number of missing data, and compared using student's T test or variance analysis.Categorical variables will be described by the total and % of each response method and the number of missing data, and compared between subgroups using Chi-2 test is the theoretical total of each class studies is greater than 5, and the Fischer test if not. The ordinal variables will be compared between subgroups using a Cochran-Mantal-Haenszel test.Hypothesis formulation will be bilateral and tests will be performed for a first species alpha risk of 5%

Documents

Study results

3351EURA_Pregnancy Final Study Report_Version 1.0_17042019 synopsis.pdf (1.42 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown