Veinotonics in pregnancy: a comparative study in the EFEMERIS database

First published: 05/12/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS5356

Study ID

16888

DARWIN EU® study

No

Study countries

France

Study description

There are few published data about possible effects of veinotonics in pregnant women. However, many French women use these medications during their pregnancy. The aim of the study is to investigate potential adverse drug

reactions of veinotonics in pregnancy. The study is conducted in EFEMERIS, a database including prescribed and dispensed reimbursed drugs during pregnancy (data from Caisse Primaire d'Assurance Maladie of Haute-Garonne) and outcomes (data from Maternal and Infant Protection Service and from Antenatal diagnosis Centre). Women who delivered from July 1st 2004 to December 31th 2007 in Haute-Garonne (time period when veinotonics were still reimbursed) and were registered in the French Health Insurance Service have been included. We compare pregnancy outcomes and newborn health between women exposed to veinotonics during pregnancy and unexposed women.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

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Last updated: 01/07/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

University of Toulouse 3 and INSERM 1027

Contact details

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Study contact

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Primary lead investigator

Christine Damase-Michel

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/09/2012

Study start date

Actual: 01/09/2012

Data analysis start date

Actual: 01/10/2012

Date of final study report

Planned: 01/04/2014

Actual: 01/04/2014

Sources of funding

- Other

More details on funding

Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM), the Clinical Research Hospital Program

Regulatory

Was the study required by a regulatory body?

No

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:

The main objective is to investigate potential adverse drug reactions of veinotonics in pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C05C) CAPILLARY STABILIZING AGENTS

CAPILLARY STABILIZING AGENTS

Population studied

Short description of the study population

Pregnant women who were either exposed or unexposed to veinotonics and who delivered from July 1st 2004 to December 31th 2007 in Haute-Garonne were registered in the French Health Insurance Service-EFEMERIS database

have been included.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

37.000

Study design details

Outcomes

all-cause pregnancy loss, preterm birth, small for gestational age, neonatal pathology, congenital malformation

Data analysis plan

We compare pregnancy outcomes and newborn health between women exposed to veinotonics during pregnancy and unexposed women. Multivariable cox proportional hazards regressions are used to estimate hazard ratios with 95 % CIs, comparing the hazard rates of pregnancy termination and preterm birth between exposed and unexposed women. Multivariable conditional logistic regressions with 95 % CIs are used to analyze the effect of exposure to veinotonics on the risks of small for gestational age, neonatal pathology, and congenital malformation.

Documents

Study publications

Lacroix I, Beau AB, Hurault-Delarue C, Bouilhac C, Petiot D, Vayssière C, Vidal...

Data management

Data sources

Data source(s)

EFEMERIS

Data sources (types)

Administrative healthcare records (e.g., claims)

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

No