A cohort study to investigate the prescribing of albiglutide among women of child-bearing age who have type 2 diabetes (201795)

First published: 15/12/2015

Last updated: 20/07/2021

Study Finalised

Administrative details

EU PAS number

EUPAS11841

Study ID

42105

DARWIN EU® study

No

Study countries

United Kingdom

Study description

With the cancellation of the Eperzan EU MA in January 2019, this post marketing study is no longer required or feasible to conduct. This is a cohort study using the UK Clinical Practice Research Datalink, CPRD, a national primary care database. A cohort of women aged 11 to 49 years with type 2 diabetes will be followed, a sub-group of women who have a pregnancy during the study period will also be identified. The objectives of this study are to: 1) assess the proportion and characteristics of women with type 2 diabetes of child-bearing age who are prescribed albiglutide, 2) assess the proportion and characteristics of women with type 2 diabetes who are prescribed albiglutide during pregnancy, 3) summarise outcomes of women prescribed albiglutide during pregnancy including reported major congenital malformations, pregnancy losses, stillbirths and neonatal deaths.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacy & Pharmacology, University of Bath

United Kingdom

First published: 30/04/2010

Last updated: 08/04/2019

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/04/2015

Actual: 17/11/2015

Study start date

Planned: 01/01/2015

Actual: 17/11/2015

Date of final study report

Planned: 21/09/2020

Actual: 10/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201795-protocol-redact.pdf (643.08 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

The primary objectives of the study are to: 1) assess the proportion and characteristics of women with type 2 diabetes of child-bearing age who are prescribed albiglutide and 2) assess the proportion and characteristics of women with type 2 diabetes who are prescribed albiglutide during pregnancy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Medicinal product name

EPERZAN

Medicinal product name, other

Tanzeum

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

ALBIGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Women aged between 11 and 49 years who have been precribed treatment for type 2 diabetes.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

10.000

Study design details

Outcomes

Surveillance in pregnant women of major congenital malformations, pregnancy losses, stillbirths and neonatal deaths.

Data analysis plan

Characteristics of women in the cohort will be described by counts and proportions of the total women in the cohort. Incidence, period prevalence and days exposed to different medications will be calculated. Women who have a pregnancy during the study period will be identified. Patient characteristics at the start date of the pregnancy and prescribing received in the three months before the pregnancy start date and each trimester of pregnancy will be tabulated as counts and percentages. Patients receiving each class of medication will be described by three month period and outcome. Comparisons will be made between the albiglutide group and those receiving other medications, if sample sizes allow. Outcomes of pregnant women will be described by counts and proportions. Foetal outcomes will be compared (where numbers permit) between the different treatment combinations received by mothers during and/or in the three months before pregnancy and those whose mothers only received metformin.

Documents

Study report

gsk-201795-clinical-study-report-redact.pdf (929.27 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Clinical Practice Research Datalink

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