Qsiva Use Among Pregnant Women and Prescribed Contraceptive Use Among Qsiva Users of Childbearing Potential: A Postmarketing Cohort Database Study in Denmark, Finland, Norway, and Sweden

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Study Planned

Administrative details

EU PAS number

EUPAS1000000886

Study ID

1000000886

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

Topiramate, a constituent of the fixed-dose combination drug Qsiva® (Vivus, B.V.), which is indicated for the management of obesity, has been shown in observational studies to be associated with an increased risk of oral clefts in infants exposed to the drug during the first trimester of pregnancy. Based on these identified risks, the summary of product characteristics (SmPC) includes contraindications for pregnant women and for women of childbearing potential who are not using effective methods of contraception. The SmPC also includes warnings and precautions for women of childbearing potential to use effective contraception while on treatment. This study will be conducted using national data sources from Denmark, Finland, Norway, and Sweden to evaluate whether use of Qsiva is consistent with the contraindications and warnings and precautions in the SmPC related to teratogenic risk.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Erik Joas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2023

Actual: 15/09/2023

Study start date

Planned: 01/12/2028

Data analysis start date

Planned: 01/03/2029

Date of interim report, if expected

Planned: 31/12/2029

Date of final study report
Planned: 30/09/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The study is funded by VIVUS LLC.

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)

Other study registration identification numbers and links

Protocol identification number: OB-906

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This will be a multi-country, non-interventional cohort study that uses secondary data from multiple sources

Main study objective:

1. Among pregnant women, to describe the prevalence of Qsiva use in the 4 weeks before pregnancy or during pregnancy (overall, and by trimester of pregnancy)
2. Among women of childbearing potential who use Qsiva, to describe use of prescribed contraceptives in the 4 weeks before treatment, during treatment, and throughout the 4 weeks after treatment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Qsiva

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

PHENTERMINE HYDROCHLORIDE

TOPIRAMATE

Anatomical Therapeutic Chemical (ATC) code

(A08AA51) phentermine and topiramate

phentermine and topiramate

Medical condition to be studied

Obesity

Complication of pregnancy

Population studied

Short description of the study population

The study will include pregnant women of all ages to assess Qsiva use during pregnancy and the preconception period, and it will include women of childbearing potential (15 years to <50 years) who use Qsiva to assess prescribed contraceptive use. As contraceptive use is anticipated to be incompletely captured in the data sources, prescribed contraceptive use will also be assessed among women of childbearing potential who use glucose-lowering medications or antihypertensive medications that are not contraindicated for use during pregnancy (i.e., comparator medications). Women in this comparator medication group will be matched to Qsiva users on age, calendar time, and Body Mass Index (BMI) classes (if records are available), at the treatment episode start date (index date for Objective 2). The

rate of contraceptive use among these women will provide context to the rate of contraceptive use among Qsiva users of childbearing potential.

Age groups

- Adults (18 to < 46 years)

Estimated number of subjects

300000

Study design details

Setting

The study is planned to be conducted 4 European countries (Denmark, Finland, Norway, and Sweden) in which Qsiva is approved. National health registers, which collect data from daily practice in the study countries, will be used to study the patient characteristics and prescribing practices in the real world.

Comparators

glucose-lowering medications and antihypertensive medications not contradicted for use during pregnancy

Outcomes

The proportion of pregnancies with any Qsiva use; the proportion and person-time exposed to Qsiva or comparator medication use in which prescribed contraceptives are used; and the proportion of episodes of Qsiva or comparator medication use with at least 1 day of prescribed contraceptive use.

Data analysis plan

Exposure to Qsiva will be identified through Anatomical Therapeutic Chemical (ATC) codes based on dispensing prescriptions. The study populations will be

characterised. For Objective 1, among pregnant women, the proportions of pregnancies and 95% CIs with any Qsiva use will be calculated overall (during pregnancy or the preconception period), and in each of the exposure windows of interest (preconception period, first trimester, second trimester, and third trimester). Separately in the Qsiva group and in the comparator medication group (Objective 2), the proportion and 95% CI of days of person-time follow-up with prescribed contraceptive use will be reported for the time periods of interest (0-4 weeks before use of Qsiva/comparator medication, during use of Qsiva/comparator medication, and 0-4 weeks after use of Qsiva/comparator medication). Additionally, in each of the 2 exposure groups, the proportion of treatment episodes of Qsiva/comparator medications with at least 1 day of contraceptive use and 95% CIs will be reported for each of the 3 time periods of interest.

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)

Danish Health Care Registries

Norwegian Health Registers

Data source(s), other

Finnish Health Registers; Swedish Health Registers

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown