# 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

**First published:** 28/01/2026

**Last updated:** 28/01/2026

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

**First published:** 12/11/2021

**Last updated:** 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

# Contact details

**Study institution contact**

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Study 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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**

300.000

## 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

## Data sources

**Data source(s)**

Danish Health Care Registries

Norwegian Health Registers

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**Data source(s), other**

Finnish Health Registers; Swedish Health Registers

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**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