QUVIVIQ® Pregnancy Registry (ID-078A403)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000033

Study ID

1000000033

DARWIN EU® study

No

Study countries

- Canada
- France
- Germany
- Italy
- Spain
- United Kingdom

United States

Study description

This is an international, longitudinal, observational study investigating pregnancy, neonatal, and infant outcomes in women exposed to QUVIVIQ during pregnancy and for whom the outcome of pregnancy is not known at the time of enrolment. The maximal study duration per woman is 21 months, and infants will be followed for 52 weeks after birth.

The primary outcome measure is the occurrence of major congenital malformations.
Secondary outcome measures comprise pregnancy complications (e.g., pre-eclampsia, pre-term labor), pregnancy outcomes (e.g., elective termination, spontaneous abortion, fetal death or stillbirth, preterm birth, full-term live birth), and infant outcomes (e.g., minor congenital malformations, small for gestational age at birth, infant mortality, infant hospitalizations for serious illness, and postnatal growth and development).

204 pregnant women exposed to QUVIVIQ, 387 pregnant women exposed to other non-orexin receptor antagonist (non-ORA) medications, and 194 pregnant women with no exposure to any insomnia medications are targeted for enrollment. The sample size was estimated to ensure sufficient power to compare the prevalence of major congenital malformations, in the infants of women exposed to QUVIVIQ vs the infants of women exposed to other non-ORA medications for insomnia, in the primary analysis using a non-inferiority testing approach.

An Adjudication Committee (individuals with expertise in obstetrics, embryology, teratology, pharmacology, epidemiology, pediatrics, clinical genetics, and insomnia) will make recommendations on data collection and

assist in the review of data and classification of specific pregnancy outcomes. Participants will be required to sign a consent form allowing collection of data from their healthcare providers. Institutional Review Board and Independent Ethics Committee approval of the registry protocol and consent form will ensure the collection of data are scientifically and ethically sound.

Study status

Ongoing

Research institutions and networks

Institutions

Idorsia Pharmaceuticals Ltd

Contact details

Study institution contact

Idorsia Clinical Trial Information

idorsiaclinicaltrials@idorsia.com

Study contact

idorsiaclinicaltrials@idorsia.com

Primary lead investigator

Idorsia Clinical Trial Information

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/10/2023

Study start date
Planned: 23/10/2023

Actual: 21/11/2024

Data analysis start date
Planned: 01/04/2025

Date of interim report, if expected
Planned: 01/04/2025

Date of final study report
Planned: 01/04/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Idorsia Pharmaceuticals Ltd

Study protocol

ID-078A403 Protocol Version 4, 23Oct2023, D-23.335-redacted.pdf (1.02 MB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Pregnancy exposure registry

Data collection methods:

Primary data collection

Study design:

International, longitudinal, observational, prospective study.

Data collection: women’s health, adverse events, pregnancy complications and -outcomes, malformations of the infants and other outcomes.

Infants will be followed for 52 weeks after birth; maximal study duration for women is 21 months.

Main study objective:

The primary objective is to compare the prevalence of major congenital malformations among prospective pregnancies in women with insomnia exposed to QUVIVIQ during pregnancy (Cohort A) and women exposed to other, non-orexin receptor antagonist medications for insomnia during pregnancy (Cohort B1).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

QUVIVIQ

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

DARIDOREXANT HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(N05CJ03) daridorexant

daridorexant

Medical condition to be studied

Maternal exposure during pregnancy

Maternal exposure before pregnancy

Complication of pregnancy

Abortion

Additional medical condition(s)

Major congenital malformations

Population studied

Short description of the study population

Women with insomnia disorder, monitored in a standard-of-care setting, and pregnant at time of enrollment (prospective pregnancies) will be assigned to a specific cohort according to the insomnia medication received. Women with insomnia disorder for whom the outcome of pregnancy is known prior to enrollment (retrospective pregnancies) will be analyzed in a separate case series.

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adolescents (12 to < 18 years)
- Adults (18 to < 65 years)

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

Special population of interest

Pregnant women

Estimated number of subjects

785

Study design details

Setting

Primary data will be collected from pregnant women with insomnia in a standard-of-care setting, where participants are seen regularly by their treating healthcare providers either for insomnia treatment or for regular assessment after insomnia treatment.

The data will be provided by the participants and healthcare providers (e.g., primary care provider, insomnia specialist, psychiatrist, obstetrician, nurse, midwife, pediatrician).

Women will be followed from enrollment through the end of their pregnancy and up to 52 weeks after the infant’s birth. Infants will be followed for 52 weeks after birth. Maternal outcomes during the postpartum follow-up year (aside from safety surveillance and lactation information from breastfeeding mothers) will not be collected.

There will be 3 study cohorts:

Cohort A

Women with insomnia exposed to QUVIVIQ during pregnancy or within 5 half-lives prior to conception.

Cohort B1

Women exposed to other, non-orexin receptor antagonist medications for insomnia during pregnancy or within 5 half-lives of the respective insomnia medication prior to conception.

Cohort B2

Women who had no exposure to any insomnia medication during pregnancy and within 5 half-lives of any insomnia medication taken prior to conception.

Comparators

Non-orexin receptor antagonist medications for insomnia (Cohort B1)

No insomnia medication (Cohort B2)

Outcomes

Primary outcome measure:

1. Major congenital malformations

Secondary outcome measures:

2. Pregnancy complications - pre-eclampsia
3. Pregnancy complications - pregnancy-induced hypertension
4. Pregnancy complications - pre-term labor
5. Pregnancy complications - gestational diabetes
6. Pregnancy outcomes - elective or therapeutic pregnancy termination
7. Pregnancy outcomes - spontaneous abortion
8. Pregnancy outcomes - fetal death or stillbirth

9. Pregnancy outcomes - live birth
10. Pregnancy outcomes - pre-term birth
11. Infant outcomes - minor congenital malformations
12. Infant outcomes - size for gestational age
13. Infant outcomes - low birth weight
14. Infant outcomes - infant death
15. Infant outcomes - hospitalization for serious illness
16. Infant outcomes - postnatal growth and development

Data analysis plan

1. Prospective pregnancies - outcome of pregnancy not known at the time of enrollment:

• In the primary analysis, the prevalence of major congenital malformations in infants of women with insomnia exposed to QUVIVIQ during pregnancy or within 5 half-lives prior to conception (Cohort A) will be compared to the prevalence in infants of women unexposed to QUVIVIQ but exposed to other, non-orexin receptor antagonist medications for insomnia during pregnancy or within 5 half-lives of the respective insomnia medication prior to conception (Cohort B1). The primary analysis will use risk ratios (one-sided 97.5% CI) to compare major congenital malformations in infants between Cohort A and Cohort B1 among women with first trimester exposure to their respective insomnia medications. Women exposed to QUVIVIQ who take other medications for insomnia at any time during pregnancy will be excluded from the primary analysis. Women with known teratogen exposure during pregnancy will be included in the primary analysis.

• In a secondary analysis, the prevalence of major congenital malformations in the infants of Cohort A will be compared to the prevalence in infants of Cohort B2 (women who had no exposure to any insomnia medication during pregnancy and within 5 half-lives of any insomnia medication taken prior to conception), as well as to infants of the overall comparator cohort (Cohort B).

2. Retrospective pregnancies - outcome of pregnancy known prior to enrollment:

• Women with insomnia exposed to QUVIVIQ during pregnancy or within 5 half-lives prior to conception, for whom the outcome of pregnancy was known prior to enrollment, will be analyzed in a separate case series. Analyses in this case series will primarily be qualitative.

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), other

QUVIVIQ® Pregnancy Registry

Data sources (types)

Pregnancy registry

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