

# QUVIVIQ® Pregnancy Registry (ID-078A403)

**First published:** 17/06/2024

**Last updated:** 13/12/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000033

### Study ID

1000000033

### DARWIN EU® study

No

### Study countries

☐ Canada

☐ France

☐ Germany

☐ Italy

☐ Spain

☐ United Kingdom

## **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.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[Idorsia Pharmaceuticals Ltd](#)

## Contact details

### **Study institution contact**

Idorsia Clinical Trial Information  
[idorsiaclinicaltrials@idorsia.com](mailto:idorsiaclinicaltrials@idorsia.com)

[Study contact](#)

[idorsiaclinicaltrials@idorsia.com](mailto: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

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**Study start date**

Planned: 23/10/2023

Actual: 21/11/2024

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**Data analysis start date**

Planned: 01/04/2025

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**Date of interim report, if expected**

Planned: 01/04/2025

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Pregnancy exposure registry

**Data collection methods:**

Primary data collection

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**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

**Name of medicine**

QUVIVIQ

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

DARIDOREXANT HYDROCHLORIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(N05CJ03) daridorexant

**Medical condition to be studied**

Maternal exposure during pregnancy

Maternal exposure before pregnancy

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**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.

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**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)

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## **Special population of interest**

Pregnant women

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## **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.

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## Comparators

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

No insomnia medication (Cohort B2)

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## 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
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## **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

### Data sources

#### **Data sources (types)**

[Pregnancy registry](#)

### Use of a Common Data Model (CDM)

#### **CDM mapping**

No

### Data quality specifications

#### **Check conformance**

Unknown

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#### **Check completeness**

Unknown

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#### **Check stability**

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No