Retrospective, non-interventional, multicenter study on the effectiveness and safety of QUVIVIQ in patients with insomnia disorder and comorbid restless legs syndrome.

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Study Planned

Administrative details

EU PAS number

EUPAS1000000859

Study ID

1000000859

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] France

- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

Study design

This is a multi-centre, retrospective, non-interventional study in patients treated with QUVIVIQ. Data will be collected retrospectively using only existing patient data found in medical records.

Research question

Is QUVIVIQ safe and efficacious in patients with insomnia disorder and comorbid restless legs syndrome (RLS)?

Main objective

To describe the safety and efficacy of QUVIVIQ in patients with insomnia disorder and comorbid RLS in a real-world setting.

Data sources

Patient data will be collected from existing medical records by participating sites, i.e., medical charts / electronic medical records, including patient self-reports/surveys, tests, and assessments.

Recruitment strategy

The investigators involved in the study will inform their eligible patients of the study and request consent for data collection.

Study status

Planned

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: 02/02/2026

Study start date

Planned: 01/04/2026

Date of final study report

Planned: 31/07/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Idorsia Pharmaceuticals Ltd

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

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

Retrospective study to collect existing data from patients with insomnia disorder and comorbid restless leg syndrome who are already treated with QUVIVIQ in neurological or sleep centres as part of their routine standard of care.

Data collection methods:

Secondary use of data

Study design:

• Study design: multi-centre, retrospective, non-interventional study with no control group.

• Data collection: existing patient data found in medical records.

• Participants: patients who have received QUVIVIQ for at least 4 weeks for insomnia disorder with comorbid restless legs syndrome.

Main study objective:

The main study objective is to describe the effects of QUVIVIQ in patients with insomnia disorder and comorbid restless legs syndrome (RLS), as follows:

• The safety of QUVIVIQ when used in patients with insomnia disorder and comorbid RLS in a real-world setting.

• The efficacy of QUVIVIQ in treating insomnia in patients with insomnia disorder and comorbid RLS in a real-world setting.

• The effect of QUVIVIQ on RLS severity in patients with insomnia disorder and comorbid RLS in a real-world setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective data collection

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

Insomnia

Restless legs syndrome

Population studied

Short description of the study population

The participants have been diagnosed with insomnia disorder and comorbid restless legs syndrome. This patient population is routinely seen in participating neurological or sleep centres in the countries where the study will be

conducted.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

90

Study design details

Setting

Study periods

(1) Baseline period: 15-week period prior to and including the date QUVIVIQ was first prescribed to the participant.

(2) Observation period: The period from the day after QUVIVIQ was first prescribed to the participant, lasting a minimum of 4 weeks and maximum of 15 weeks. Ends with the signing of the informed consent form (ICF).

Patient population

• Aged ≥ 18 years at the date of first prescription of QUVIVIQ.

• Diagnosed with insomnia disorder, characterised by difficulty initiating and/or maintaining sleep, and/or early morning awakenings, occurring 3 or more nights

per week for at least 3 months with daytime symptoms.
• Diagnosed with comorbid, clinically stable, restless legs syndrome (RLS), with no change in RLS medication during the 3 months prior to initiation of QUVIVIQ and no signs of augmentation.
• Prescribed QUVIVIQ 50 mg at least 4 weeks prior to signing the ICF.
• Clinically assessed while treated with QUVIVIQ at least once between 4 and 15 weeks after first prescription of QUVIVIQ.

Outcomes

Data collection will include variables assessed or measured as part of standard clinical care as per local practice. Data will not be generated for the sole purpose of the study.

Endpoint definitions
• Safety: All relevant medical events that occur from baseline to the last clinical on-treatment assessment between 4 and 15 weeks after first prescription of QUVIVIQ.
• Efficacy in treating insomnia: Change in Insomnia Severity Index© (ISI©) score from baseline to the last clinical on-treatment assessment between 4 and 15 weeks after first prescription of QUVIVIQ.
• Effect on restless legs syndrome (RLS) severity: Change in International Restless Legs Study Group Severity Rating Scale (IRLS) total or local score from baseline to the last clinical on-treatment assessment between 4 and 15 weeks after first prescription of QUVIVIQ.

Data analysis plan

Full analysis set
• All participants for whom informed consent was obtained and who received QUVIVIQ for at least 4 weeks.

Change from baseline in Insomnia Severity Index© score and International Restless Legs Study Group Severity Rating Scale total score
• One-sample t-test (95% confidence intervals for the mean change).

Adverse events (AEs)
• Number and percentage of participants experiencing any AE during the baseline period (i.e., AEs starting prior to and including the first prescription date of QUVIVIQ).
• Number and percentage of participants experiencing any AE during the observation period (i.e., from the day after QUVIVIQ was first prescribed to the participant: a minimum of 4 weeks to a maximum of 15 weeks).

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 sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Patient surveys

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