Retrospective, non-interventional multicenter study on the effect of QUVIVIQ in patients with insomnia disorder with comorbid anxiety and/or depression disorders

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000594

Study ID

1000000594

DARWIN EU® study

No

Study countries

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 anxiety and/or depression disorders in clinical practice?

Main objective

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

Data sources

Patient data will be collected from existing medical records by the 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

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: 14/07/2025

Study start date

Planned: 30/09/2025

Actual: 31/08/2025

Data analysis start date

Planned: 01/12/2025

Date of final study report
Planned: 31/12/2026

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 anxiety and/or depression disorders who are already treated with QUVIVIQ in psychiatric, sleep or neurological 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 anxiety and/or depression.

Main study objective:

The main objective of the study is to describe the effects of QUVIVIQ in patients with insomnia disorder and comorbid anxiety and/or depression disorders, as

follows:

• The safety of QUVIVIQ in patients with insomnia disorder and comorbid anxiety and/or depression in a real world setting.

• The efficacy of QUVIVIQ in treating insomnia in patients with insomnia disorder and comorbid anxiety and/or depression in a real-world setting.

• The effect of QUVIVIQ on comorbid anxiety and/or depression in patients with insomnia disorder in a real world setting.

Study Design

Non-interventional study design

Cohort

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

Anxiety disorder

Depression

Mixed anxiety and depressive disorder

Population studied

Short description of the study population

The participants have been diagnosed with insomnia disorder and comorbid anxiety and/or depression. This patient population is routinely seen in participating psychiatric, 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

220

Study design details

Setting

Study periods

(1) Baseline period: 15-week time-period prior to the date QUVIVIQ was first prescribed to a patient.

(2) QUVIVIQ prescription date: The date that QUVIVIQ was first prescribed to the patient.

(3) Observation period: The period from when QUVIVIQ was first prescribed to the patient up until signature of the informed consent form (ICF), allowing retrospective data collection.

Patient population

• Aged ≥ 18 years at the start of treatment with QUVIVIQ.

• Diagnosed with insomnia disorder, characterised by difficulty initiating and/or maintaining sleep, occurring 3 or more nights per week for at least 3 months with daytime symptoms.

• Diagnosed with comorbid anxiety and/or depression.

• Prescribed QUVIVIQ and treated for at least 4 weeks.

• Clinically assessed while treated with QUVIVIQ at least once between 4 and 15 weeks after first prescription of QUVIVIQ.

Outcomes

Only variables already recorded in the patient’s medical records will be collected.

Endpoint definitions

For all patients

• All adverse events, including any events of special interest (suicidal ideation, sleep paralysis and hallucinations, and somnolence) occurring during the baseline period and/or observation period.

• Change in Insomnia Severity Index© score from baseline to the last clinical on-treatment assessment between 4 and 15 weeks after first prescription of QUVIVIQ.

For patients diagnosed with comorbid anxiety
• Change in Self-Reported Anxiety Scale score or any local anxiety scale score from baseline to the last clinical on-treatment assessment between 4 and 15 weeks after first prescription of QUVIVIQ.

For patients diagnosed with comorbid depression
• Change in Beck Depression Inventory-II or any local depression scale 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.

Analysis of Self-Reported Anxiety Scale (SAS) scores: only patients diagnosed with comorbid anxiety.

Analysis of Beck Depression Inventory-II (BDI-II) scores: only patients diagnosed with comorbid depression.

Subgroup analyses: participants with insomnia disorder and: (1) comorbid anxiety only, (2) comorbid depression only, (3) comorbid anxiety and depression.

Change from baseline in Insomnia Severity Index©-, BDI-II- and SAS scores: one-sample t-test (95% confidence intervals for the mean change).

Adverse events (AEs): number and percentage of patients experiencing any AE and each AE of interest during the pre-treatment period (i.e., AE ongoing at first prescription date of QUVIVIQ) and on-treatment period. The same AE summaries will be generated for the subgroup of patients diagnosed with comorbid anxiety, and for the subgroup of patients diagnosed with comorbid depression.

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