A multinational Post-Authorisation Safety Study evaluating real-world treatment in patients receiving Yselty® (linzagolix choline) for moderate to severe symptoms of uterine fibroids - DAISY

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000924

Study ID

1000000924

DARWIN EU® study

No

Study countries

Germany

Italy

Poland

Spain

United Kingdom

Study description

Post-Authorization Safety Study to assess the long-term safety of Yselty® when used in real life clinical practice.

Study status

Planned

Contact details

Study institution contact

Marina Todorova qqpv.eu@theramex.com

Study contact

qqpv.eu@theramex.com

Primary lead investigator

Marina Todorova

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/05/2025

Actual: 23/05/2025

Study start date

Planned: 15/03/2026

Data analysis start date
Planned: 15/01/2028

Date of interim report, if expected
Planned: 30/12/2028

Date of final study report
Planned: 31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Theramex Ireland Limited

Study protocol

DAISY PASS Protocol_v6.0_20250401_clean (1).pdf (646.97 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Non-interventional, prospective, multicentre, multinational, cohort study based on primary data collection

Main study objective:

To evaluate routinely collected data on long-term safety (>12 months) in relation to BMD with use of Yselty® 200 mg (with ABT) and 100 mg (with and without ABT) dosing regimens

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

YSELTY

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

LINZAGOLIX CHOLINE

Anatomical Therapeutic Chemical (ATC) code

(H01CC04) linzagolix

linzagolix

Medical condition to be studied

Leiomyoma

Population studied

Short description of the study population

Adult women of reproductive age with moderate to severe symptoms of Uterine fibroids

Age groups

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

Estimated number of subjects

1.000

Study design details

Setting

Adult women in reproductive age with moderate to severe symptoms of Uterine fibroids recruited and enrolled in hospital settings qualified to conduct the study. The recruitment period is planned for 18 months starting from Q1/Q2 2026. The inclusion and exclusion criteria are :

Inclusion criteria

• Signed informed consent

• Females of reproductive age ≥18 years

• New users of Yselty® (not longer than 3 months after treatment initiation)

• Indication of moderate to severe symptoms of uterine fibroids

Exclusion criteria

• Patients who have ever used another GnRH antagonist (e.g., relugolix, elagolix) before enrolment

• Contraindications as per the approved SmPC

• Enrolment in a prior clinical trial with Yselty®

• Patients participating in an investigational program with interventions outside of routine clinical practice

There is no treatement arms, nor comparator group as part of the study

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Comparators

N/A

Outcomes

N/A

Data analysis plan

Statistical analyses will be of an exploratory and descriptive nature. All variables will be analysed descriptively with appropriate statistical methods:

categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by descriptive statistics (i.e., number of patients, mean, standard deviation, minimum, median, quartiles, and maximum).
Continuous variables will be summarised by absolute value and changes from baseline per analysis time point, if applicable. Missing data in non-interventional research are informative categories indicating coverage of services.
No imputation of missing information will be applied.
The number and frequency of patients with missing data will be presented as separate category.

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

prospective patient medical dossier-based data collection

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

CDISC SDTM

CDM website

https://www.cdisc.org/standards/foundational/sdtm

CDM version

SDTM IG:3.4

Data quality specifications

Check conformance

Unknown

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model

after creation of study variables

Data characterisation details

Data quality Checks will be performed according to internal Standard Operation Procedures which describe the programming and validation of data sets and by using PINNACLE 21 Enterprise version to perform conformance checks of SDTMs and ADaMs against CDISC standards.