

# 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

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### Study ID

1000000924

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### DARWIN EU® study

No

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### Study countries

 Germany

 Italy

 Poland

 Spain

 United Kingdom

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## Study description

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

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## Study status

Planned

## Contact details

### Study institution contact

Marina Todorova [qqpv.eu@theramex.com](mailto:qqpv.eu@theramex.com)

**Study contact**

[qqpv.eu@theramex.com](mailto: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

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### Study start date

Planned: 15/03/2026

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**Data analysis start date**

Planned: 15/01/2028

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**Date of interim report, if expected**

Planned: 30/12/2028

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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

LINZAGOLIX CHOLINE

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**Anatomical Therapeutic Chemical (ATC) code**

(H01CC04) linzagolix

linzagolix

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**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

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**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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**Estimated number of subjects**

1000

## 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  $\geq 18$  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 treatment arms, nor comparator group as part of the study

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## **Comparators**

N/A

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## **Outcomes**

N/A

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## **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

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

[Non-interventional study](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

Yes

## **CDM Mappings**

### **CDM name**

CDISC SDTM

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### **CDM website**

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

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### **CDM version**

SDTM IG:3.4

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes

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**Data characterisation moment**

after extract-transform-load to a common data model

after creation of study variables

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**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.