# Fezolinetant Experience for the Treatment of Vasomotor Symptoms Associated with Menopause Among Women in a German Real-life Setting

**First published:** 26/09/2024

**Last updated:** 15/05/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000132

**Study ID**

1000000132

**DARWIN EU® study**

No

**Study countries**

☐ Germany

**Study description**

This study is for women in Germany who are going through menopause. They have symptoms including hot flashes and night sweats (also called vasomotor symptoms). Their doctor has decided to give them fezolinetant tablets to help treat these symptoms.
Fezolinetant tablets do not contain hormones. Fezolinetant tablets have been approved in some countries to treat hot flashes and night sweats.

**Study status**

Ongoing

## Research institutions and networks

### Institutions

Astellas Pharma Europe Ltd.

## Contact details


**Study institution contact**

Clinical Trial Registration Department

clinicaltrialregistration@astellas.com

**Study contact**

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**Primary lead investigator**

Regina Schaetzle

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Actual: 22/07/2024

**Study start date**
Actual: 18/06/2024

**Data analysis start date**
Planned: 17/04/2026

**Date of final study report**
Planned: 15/09/2026

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Astellas Pharma Europe Ltd.

# Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Other study registration identification numbers and links

2693-MA-3549

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

**Study design:**

This is a decentralized clinical trial, single arm prospective study using Real World Evidence with no Biospecimen Retention.

**Main study objective:**

The goal of this study is to learn about the value of fezolinetant tablets in treating hot flashes and night sweats that women in Germany experience during menopause.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

VEOZA

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

FEZOLINETANT

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**Anatomical Therapeutic Chemical (ATC) code**

(G02CX06) fezolinetant

fezolinetant

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**Medical condition to be studied**

Menopausal symptoms

## Population studied

**Short description of the study population**

The study population will consist of women who are experiencing VMS and have been prescribed fezolinetant for the treatment of VMS associated with menopause via an independent decision by the treating physician as per routine clinical practice.

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**Age groups**

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

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**Special population of interest**

Other

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**Special population of interest, other**

Menopausal women

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**Estimated number of subjects**

334

## Study design details

**Setting**

The women that want to take part in the study will take fezolinetant tablets for their hot flashes and night sweats. This study is about collecting information only. The individual’s doctor decides on treatment, not the study sponsor (Astellas).

The study will last about 6 months (24 weeks). During the study, the women taking part will complete up to 5 virtual reviews. The virtual reviews will ask the

women to complete 3 – 5 surveys.
At the first virtual review the women will be asked about their health and other medicines they have taken or are taking.
The surveys will ask the women about their hot flashes and night sweats, other menopause symptoms, and how these symptoms affect their health and daily life.
After the first or second virtual review the women will take their first dose of fezolinetant tablets and continue taking fezolinetant as explained by their doctor.
The women will have 3 virtual follow-up reviews at about 1 week, 3 months (12 weeks), and 6 months (24 weeks) after their first dose of fezolinetant tablets.
The women will be asked when they took their fezolinetant tablets or if they stopped taking them.

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**Comparators**

None

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**Outcomes**

Primary:

• Response of “moderately better” or “much better” at week 24, measured by Patient Global Impression of Change of Vasomotor Symptoms (PGI-C VMS)

Secondary:

• Response of “moderately better” or “much better” at week 1 and week 12, measured by PGI-C VMS
• Change on the Menopause-Specific Quality of Life Domain (MENQoL) 1-week recall vasomotor symptoms (VMS) domain score from baseline to week 12 and from baseline to week 24
• Change on the MENQOL 1-week recall total score (full questionnaire) from

baseline to week 12 and from baseline to week 24
• Response of “moderately better” or “much better” at weeks 1, 12 and 24, measured by the Patient Global Impression of Change of Sleep Disturbance (PGI-C SD)
• Change on the Patient-Reported Outcomes Measurement Information System, Sleep Disturbance - short Form 8b (PROMIS SD SF 8b) total score from baseline to week 12 and from baseline to week 24
• Response of “very satisfied”, “somewhat satisfied”, “undecided”, “somewhat unsatisfied” or “very unsatisfied” on treatment satisfaction at week 12 and week 24
• Discontinuation of fezolinetant (yes/no)
• Reason for discontinuation
• Treatment switching for VMS associated with menopause (yes/no)
• Occurrence of each adverse event (AE) (yes/no)
• Occurrence of each SAE (yes/no)

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**Data analysis plan**
This is a single arm, non-interventional observational study, with no hypothesis testing. The sample size is based on primary estimands and assumes approximately 25% discontinuation prior to week 24.

The primary estimand is the Treatment Policy estimand, which ignores intercurrent events, including changes in treatment. Missing data will be imputed.

Supplemental analyses are proposed, to use a Hypothetical estimand (data occurring after intercurrent events are set to missing), and a Composite estimand (any occurrence of an intercurrent event leads to the participant being considered a non-responder).

# 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.

## 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