

# A Randomized, Placebo-Controlled, Parallel-Design, Exploratory Study to Evaluate the Efficacy of fremanezumab in Subjects with Rosacea

**First published:** 15/06/2021

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS41590

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### Study ID

46596

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

Lay language title: A study of fremanezumab in patients with moderate to severe rosacea Phase 1b interventional study Inclusion: Males and non-pregnant females with moderate or severe rosacea, 18 years and older Exclusion: Other rosacea treatments within 14 days Known sensitivity to fremanezumab Study completion expected November 2021 IPD sharing statement: Qualified researchers may request access to patient level data and related study documents including the study protocol and the statistical analysis plan. Requests will be reviewed for scientific merit, product approval status, and conflicts of interest. Patient level data will be de-identified and study documents will be redacted to protect the privacy of trial participants and to protect commercially confidential information. Please email USMedInfo@tevapharm.com to make your request.

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### **Study status**

Finalised

## Contact details

### **Study institution contact**

Juline Bryson [juline.bryson@tevapharm.com](mailto:juline.bryson@tevapharm.com)

**Study contact**

[juline.bryson@tevapharm.com](mailto:juline.bryson@tevapharm.com)

### **Primary lead investigator**

Juline Bryson

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 06/01/2021

Actual: 02/02/2021

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**Study start date**

Planned: 16/06/2021

Actual: 16/06/2021

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**Date of final study report**

Planned: 15/02/2022

Actual: 22/03/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva Pharmaceuticals

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Clinical trial

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To compare efficacy of active medication over placebo

### Study Design

**Clinical trial phase**

Human pharmacology (Phase I)

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### **Clinical trial randomisation**

Randomised clinical trial

## Study drug and medical condition

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

FREMANEZUMAB

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### **Medical condition to be studied**

Rosacea

## Population studied

### **Short description of the study population**

The study included males and non-pregnant females aged 18 years or older with moderate or severe rosacea.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Other

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## Special population of interest, other

Patients with rosacea

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### Estimated number of subjects

40

## Study design details

### Outcomes

Proportion of patients considered a treatment success in each group (test and placebo), Number of patients with adverse events in each group

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### Data analysis plan

Descriptive statistics (n, mean, standard deviation, standard error of mean, median, minimum, and maximum) will be provided for actual values

## 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)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

## **Use of a Common Data Model (CDM)**

### **CDM mapping**

No

## **Data quality specifications**

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No