

# Levocetirizine/cetirizine levels in human milk – an observational, clinical study among breastfeeding women

**First published:** 11/03/2022

**Last updated:** 15/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS46213

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### Study ID

46214

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### DARWIN EU® study

No

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### Study countries

Norway

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### Study description

This is a open-label observational study conducted to determine (levo)cetirizine levels in breast milk of breastfeeding women and monitor adverse events in nursing infants. In total, 25 to 40 lactating women in Norway will be recruited. The study is part of the IMI ConcePTION project, as a demonstration project in WP4 of ConcePTION.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo

Norway

**First published:** 19/10/2016

**Last updated:** 06/11/2025

**Institution**

**Educational Institution**

**ENCePP partner**

### Networks

ConcepTION

**First published:** 01/02/2024

**Last updated:** 01/02/2024

## Contact details

### Study institution contact

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Study contact

[h.m.e.nordeng@farmasi.uio.no](mailto:h.m.e.nordeng@farmasi.uio.no)

### Primary lead investigator

Hedvig Nordeng

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/03/2019

Actual: 01/04/2019

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### Study start date

Planned: 28/04/2021

Actual: 01/07/2021

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### Date of final study report

Planned: 01/03/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

IMI 2- Grant agreement No 821520

## 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

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Other

#### **If 'other', further details on the scope of the study**

Human lactation study

**Main study objective:**

Quantifying (levo)cetirizine excretion into human milk. Calculation of the relative infant dose (RID). Monitor the safety of (levo)cetirizine during breastfeeding.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational human lactation study

## Study drug and medical condition

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

CETIRIZINE

## Population studied

**Age groups**

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

25

## Study design details

## Outcomes

Variability of concentration of (levo)cetirizine in human milk samples. Maternal self-reported adverse events among breastfed infants. Maternal self-reported perceived changes in milk production

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## Data analysis plan

Calculation of RID, pharmacokinetic modeling

## 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

25 to 40 lactating women using levocetirizine or cetirizine will be included in the study.

## 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