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

PURI

https://redirect.ema.europa.eu/resource/46214

EU PAS number

EUPAS46213

Study ID

46214

DARWIN EU® study

No

Study countries

☐ Norway

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.

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: 08/11/2016

Institution | Educational Institution | ENCePP partner

Networks

ConcepTION

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hedvig Nordeng

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2019

Actual: 01/04/2019

Study start date

Planned: 28/04/2021

Actual: 01/07/2021

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

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

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No