A Study to Assess the Amount of Palopegteriparatide in Breast Milk of Lactating Females Requiring YORVIPATH® (Palopegteriparatide)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000922

Study ID

1000000922

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is an observational, opportunistic lactation study to be conducted in lactating female participants who are currently receiving therapeutic doses of YORVIPATH® as part of their usual care and who have chosen to breastfeed their infant(s). The potential transfer of palopegteriparatide (YORVIPATH®) into breast milk will be assessed.

Study status

Planned

Research institutions and networks

Institutions

Ascendis Pharma

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Institution

Contact details

Study institution contact

Medical Director

asnd_registryinquiries@ascendispharma.com

Study contact

asnd_registryinquiries@ascendispharma.com

Primary lead investigator

Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/09/2025

Study start date
Planned: 13/02/2026

Date of final study report
Planned: 01/11/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ascendis Pharma

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To evaluate the transfer of palopegteriparatide (YORVIPATH®) into human breast milk of lactating female participants who are breastfeeding while being treated with YORVIPATH®.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

YORVIPATH

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

PALOPEGTERIPARATIDE

Anatomical Therapeutic Chemical (ATC) code

(H05AA05) palopegteriparatide

palopegteriparatide

Medical condition to be studied

Hypoparathyroidism

Population studied

Short description of the study population

Lactating female participants who are currently receiving therapeutic doses of YORVIPATH® as part of their usual care and who have chosen to breastfeed their infant(s).

Age groups

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

Special population of interest

Pregnant women

Estimated number of subjects

10

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)

Electronic healthcare records (EHR)

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

Unknown