A Global Pregnancy Registry to Assess Maternal, Fetal, and Infant Outcomes Following Exposure to YORVIPATH® (Palopegteriparatide) During Pregnancy and Breastfeeding

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Study Planned

Administrative details

EU PAS number

EUPAS1000000921

Study ID

1000000921

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of this registry study is to collect both prospective and retrospective data in women exposed to palopegteriparatide during pregnancy to assess risk of pregnancy and maternal complications, and adverse effects on the developing fetus, neonate, and infant and to assess infant outcomes through at least the first year of life.

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: 15/08/2036

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 type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

1. The number of fetuses as reported by HCP

2. Pregnancy outcomes

• Live birth (preterm delivery, full-term delivery)

• Spontaneous abortion

• Pregnancy termination

• Fetal death/stillbirth

• Molar or ectopic pregnancy

3. Number of congenital malformations identified in the developing fetus, neonate, or infant

4. Descriptive statistics of adverse events (AEs), including serious adverse events (SAEs)

5. Number of hospitalizations including reasons for hospitalization

6. Descriptive statistics of growth and development milestones as described by the Centers for Disease Control and Prevention (CDC 2021) or other accepted standard assessment

7. Number of signs of hypocalcemia or hypercalcemia

8. Descriptive statistics of infant developmental deficiency (CDC 2021)

9. Descriptive statistics of postnatal growth deficiency or failure to thrive (FTT)

10. Descriptive statistics of neonatal and infant mortality

11. Maternal complications of pregnancy

Including but not limited to

• Premature rupture of membranes (PROM)

• Preterm PROM (PPROM)

• Pre-eclampsia

• Gestational hypertension

• Eclampsia

• Proteinuria

• Gestational diabetes

• Intrauterine growth restriction (IUGR)

• Polyhydramnios

• Preterm delivery

• Measures of fetal growth deficiency (e.g., small for gestational age)

12. Other maternal events of interest

Number of

• AEs, including SAEs

• Events specific to hypoparathyroidism (e.

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

Pregnant women exposed to palopegteriparatide (YORVIPATH®) during pregnancy. Palopegteriparatide (YORVIPATH®) prescribed as per normal clinical practice.

Age groups

- Adolescents (12 to < 18 years)
- 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

50

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