European non-interventional post-authorization safety study (PASS) to evaluate cardiovascular (CV) events and all-cause mortality in patients newly exposed to abaloparatide or teriparatide

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000613

Study ID

1000000613

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

☐ Italy

☐ Spain

Study description

Research question: Is the risk of major cardiovascular events (MACE-1 and MACE-2), arrhythmia, and all-cause mortality (including CV death) associated with abaloparatide use in routine clinical practice in Europe not different relative to teriparatide?

Study status

Planned

Research institutions and networks

Institutions

Pharmaco- and Device epidemiology, University of Oxford

☐ United Kingdom

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Institution **Educational Institution** **ENCePP partner**

Theramex Ireland Ltd

Contact details

Study institution contact

Trishna Rathod-Mistry trishna.rathod-mistry@ndorms.ox.ac.uk

Study contact

trishna.rathod-mistry@ndorms.ox.ac.uk

Primary lead investigator

Trishna Rathod-Mistry 0000-0002-6369-4746

Primary lead investigator

ORCID number:

0000-0002-6369-4746

Study timelines

Date when funding contract was signed

Actual: 19/03/2025

Study start date

Planned: 01/04/2025

Date of interim report, if expected

Planned: 31/12/2026

Date of final study report

Planned: 31/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The study is sponsored by Theramex Ireland Limited.

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

An international network cohort study using data mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The study will use a new users design and compare new users of abaloparatide to new users of teriparatide.

Main study objective:

The primary objective of this study is to evaluate the risk of CV events of MACE-1 (defined as events of myocardial infarction (MI), stroke, or CV death), potentially associated with the use of abaloparatide, in comparison with the use of teriparatide in routine clinical practice in Europe.

The study endpoints corresponding with this objective are:

• incidence rate (IR) of MACE-1 in:

o new abaloparatide users in the indicated population in Europe as per the Summary of Product Characteristics (SmPC);

o and separately in a cohort of new users of teriparatide who would also fulfil the indication/contraindications for abaloparatide in Europe.

o groups stratified by age;

o groups stratified by pre-specified key CV risk factors (such as hypertension, hy-percholesterolemia, diabetes, etc.).

• estimates of comparative risk, using an active comparator, new user design, of MACE-1, in new abaloparatide users in the indicated population in Europe as per the SmPC compared with new users of teriparatide (active comparator) with similar baseline characteristics.

The secondary objectives of this study are to evaluate the risk of MACE-2

(defined as events of MI, stroke, or all-cause mortality including CV death), MI, stroke, CV death, all-cause mortality including CV death, and arrythmia potentially associated with the use of abaloparatide in comparison with the use of teriparatide in routine clinical practice in Europe. The study endpoints corresponding with this objective are:
• incidence rates (IR) of the following CV events: MACE-2, MI, stroke, CV death, all-cause mortality including CV death, and arrhythmia in:
o new abaloparatide users in the indicated population in Europe as per the Summary of Product Characteristics (SmPC);
o and separately in a cohort of new users of teriparatide who would also fulfil the indication/contraindications for abaloparatide in Europe.
o groups stratified by age.
o groups stratified by pre-specified key CV risk factors (such as hypertension, hypercholesterolemia, diabetes, etc.).
• estimates of comparative risk, using an active comparator, new user design, of CV events MACE-2, MI, stroke, CV death, all-cause mortality including CV death, and arrhythmia in new abaloparatide users in the indicated population in Europe as per the SmPC compared with new users of teriparatide (active comparator) with similar baseline characteristics.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name

ELADYNOS

Medicinal product name, other

ABALOPARATIDE

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

ABALOPARATIDE

Anatomical Therapeutic Chemical (ATC) code

(H05AA04) abaloparatide

abaloparatide

Medical condition to be studied

Cardiovascular disorder

Population studied

Short description of the study population

The study population represents the indicated population for abaloparatide in Europe as per the SmPC and therefore comprises postmenopausal women who are first prescribed abaloparatide or teriparatide medication. Patients must have been continuously registered in the data source for at least 12 months prior to the first recorded prescription and are at least 50 years of age on the date of the prescription.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest, other

Women aged 50 years and over

Study design details

Setting

Data from four healthcare databases will be obtained.

Outcomes

Primary outcome: incidence of MACE-1 (defined as events of MI, stroke, or CV death).

The secondary outcomes are the incidence of: MI, Stroke, Death associated due to CV causes, All-cause mortality, MACE-2 (defined as events of MI, stroke, or death (all cause including CV death)), Cardiac arrhythmias.

Data analysis plan

The proposed comparative safety analysis aims to assess whether in women with OP at high risk for fracture, treatment with abaloparatide is associated with an increased risk of CV events of MI, stroke, all-cause mortality (including CV death) and arrhythmia compared to users of teriparatide similar to the indicated population for abaloparatide in Europe as per the SmPC and with similar baseline characteristics.

Incidence rates and 95 % confidence intervals (CIs) for each outcome will be calculated for Abaloparatide and Teriparatide users.

For the comparative safety analysis, propensity score matching will be used to

match patients using abaloparatide to alendronate users. Cox regression models will be used to calculate hazard ratios and 95 % CIs for each outcome in the propensity-matched cohorts. Meta-analysis random effect model may be used to pool the individual hazard ratios together.

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.

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown