PAR-R13-001: PARADIGHM (Physicians Advancing Disease Knowledge in Hypoparathyroidism): A Registry for Patients with Chronic Hypoparathyroidism

First published: 16/03/2018

Last updated: 18/10/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS16927

Study ID

45599

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Canada
- ☐ Denmark

- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study description

The main aim of this study is to find out the long-term safety and effectiveness profile of recombinant human parathyroid hormone (1-84) (rhPTH1-84) treatment in participants with chronic hypoparathyroidism under conditions of routine clinical practice. Participants will be treated according to their clinic's standard practice determined by the treating doctors. Each participant will fill out a study questionnaire during a routine doctor visit.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/05/2013

Study start date

Planned: 01/07/2013

Actual: 01/07/2013

Date of final study report

Planned: 01/06/2035

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

Study protocol

PAR-R13-001-protocol-original-redact.pdf(999.4 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/PSP/S/0058.1

Other study registration identification numbers and links

NCT01922440,https://clinicaltrials.gov/ct2/show/NCT01922440?term=PAR-R13-001&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To characterize and describe the long-term safety and effectiveness profile of rhPTH(1-84) treatment in patients with chronic hypoparathyroidism under conditions of routine clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, Non-interventional Study (Registry)

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H05AA03) parathyroid hormone

parathyroid hormone

Medical condition to be studied

Hypoparathyroidism

Population studied

Age groups

Adults (18 to < 46 years)

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

Special population of interest, other

Patients with hypoparathyroidism

Estimated number of subjects

1339

Study design details

Outcomes

- Hypoparathyroidism Laboratory Test - Renal Function - Incidence Rate of the Renal Events - Incidence Rate of the Soft Tissue Calcifications (site) - Incidence Rate of the Cataract - Incidence Rate of the Bone Fractures (site) - Incidence Rate of the Cardiovascular Events - Number of Participants With Adverse Events and Serious Adverse Events, - Health-related Quality of Life (HRQoL) - Disease-specific Patient-reported Outcome Measures - Rate of Hospitalization/Emergency Room (ER) Visits

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Data analysis plan

Data will primarily be summarized with descriptive statistics comprising the number of observations (n), mean, standard deviation, median, minimum, and maximum for continuous variables, and counts and percentages for categorical variables. Person-years of follow-up and incidence rates of prospective events will be calculated.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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