TAK-834-4008: Quantitative Testing of Patient and Healthcare Provider Knowledge, Attitudes, and Behavior About NATPARA® (Parathyroid Hormone) for Injection, for Subcutaneous Use (NATPARA KAB)

First published: 26/09/2022

Last updated: 07/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49588

EU PAS number

EUPAS48713

Study ID

49588

DARWIN EU® study

No

Study countries

United States

Study description

This main aim of this study is to check level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of NATPARA. The survey will be done via internet, telephone, or paper and participants will be able to choose the method that is preferred.

Study status

Ongoing

Research institutions and networks

Institutions

Shire

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Shire

Study contact

ClinicalTransparency@shire.com

Primary lead investigator

Study Contact Shire

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/09/2015

Study start date
Actual: 01/09/2015

Date of final study report
Planned: 31/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

NCT05556629 - https://clinicaltrials.gov/ct2/show/NCT05556629,,https://clinicaltrials.takeda.com/study-detail/7e4fd13264a44033?idFilter=%5B%22TAK-834-4008%22%5D

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

Knowledge, Attitude, Behavior Survey

Main study objective:

The main aim of this study is to check level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of NATPARA. The survey will be done via internet, telephone, or paper and participants will be able to choose the method that is preferred.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

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)

Estimated number of subjects

200

Study design details

Outcomes

Number of Participants and Prescribers Providing Correct Responses to Questions, Number of Participants and Prescribers Providing At Least 80 Percent (%) Correct Responses to Each Key Risk Message and who Demonstrated Understanding of Each Key Risk Message

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Data analysis plan

Data from all respondents who access the survey will be collected. Only data from those survey respondents who were eligible to participate in the survey and answered all questions (“completers”) will be analyzed. Counts and percentages will be calculated for each question/item in the questionnaire. P-values for comparison of how representative the respective survey respondents are of the respective stakeholder population will be obtained from the chi-square test.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

The primary source for this study is the Knowledge, Attitudes and Behavioral (KAB) and Risk Evaluation and Mitigation Strategy (REMS) surveys. Survey will be administered via internet, phone, or paper.

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