Persistence and compliance to anti-osteoporosis medications in the United Kingdom using the Clinical Practice Research Datalink (CPRD) (20160192)

First published: 04/04/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18402

Study ID

25344

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

We aim to evaluate persistence and compliance to osteoporosis therapies in post-menopausal women (including premature or surgery-induced menopause) who receive at least one prescription for any licensed medication between 2010 and 2015. Patients with history of cancer, metabolic bone disease before or on the index date, less than 12 months of medical history before the index date and less than six months of medical records after the index date will be excluded. The primary objective of the study will be to estimate the persistence and refill compliance of osteoporosis therapies (both oral and parenteral) over 6, 12, 18, 24 month follow-up periods. Secondary objectives will be to estimate persistence and refill compliance over the same time periods in postmenopausal women who are treatment-naïve and non-naïve treated. Outcomes will be assessed for the entire study population and for each of the cohorts of interest. All summaries of the data will be descriptive in nature. We will also present effects of various patient characteristics on the persistence and compliance outcome (e.g. age groups, comorbidities, prior therapies, and concomitant medications).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/05/2016

Actual: 20/05/2016

Study start date
Planned: 01/05/2017

Actual: 01/05/2017

Data analysis start date
Planned: 01/06/2017

Actual: 01/06/2017

Date of final study report
Planned: 30/06/2018

Actual: 28/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160192 CPRD study protocol 29th March 2017 (redacted).pdf(552.84 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Persistence and compliance of osteoporosis medications

Data collection methods:

Secondary use of data

Main study objective:

To evaluate whether persistence and compliance to osteoporosis therapies in postmenopausal women with osteoporosis has improved by the introduction of new parenteral therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DENOSUMAB

ALENDRONATE SODIUM TRIHYDRATE

ZOLEDRONATE DISODIUM HYDRATE

IBANDRONATE SODIUM HYDRATE

RISEDRONATE SODIUM

STRONTIUM RANELATE

ETIDRONATE DISODIUM

RALOXIFENE

TERIPARATIDE

Medical condition to be studied

Osteoporosis postmenopausal

Population studied

Short description of the study population

Postmenopausal women in the UK from CPRD.

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

Renal impaired

Estimated number of subjects

60000

Study design details

Outcomes

To estimate persistence and refill compliance to osteoporosis therapies (both oral and parenteral) in a real-world setting over 6, 12, 18, 24 month follow-up periods in postmenopausal women. To estimate persistence and refill compliance to osteoporosis therapies (both oral and parenteral) in a real-world setting over 6, 12, 18, 24 month follow-up periods in postmenopausal women who are treatment-naïve and also in those who are non-naïve treated.

Data analysis plan

Analyses supporting the primary and secondary objectives will describe persistence (quantified using Estimated Level of Persistence with Therapy (ELPT)) and compliance (quantified using medication possession ratio (MPR) for oral therapies and medication coverage ratio (MCR) for parenteral therapies) in

patients starting and finishing any new osteoporosis therapy during 2010-2015. Outcomes will be assessed for the entire study population and separately, for treatment naïve and non-naïve treated patients with persistence and compliance assessed over 6, 12, 18, 24 months, 3 and 5 years. All summaries of data will be descriptive in nature. Categorical variables (including the primary outcome), the frequency and percentage, with 95% confidence interval, will be presented. Statistics for continuous variables will include the number of subjects, mean, median, standard deviation or standard error, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum.

Documents

Study results

Study 20161092 ORSR Abstract for CTD EnCePP 27th July 2018 redacted.pdf (140.26 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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