Healthcare Professional and Patient Surveys to Evaluate the Effectiveness of the Risk Minimisation Educational Materials for Certolizumab Pegol (CZP; CIMZIA®)

First published: 29/08/2016

Last updated: 04/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14867

Study ID

32795

DARWIN EU® study

No

Study countries

Denmark

France

Germany

Greece

Norway

Sweden

United Kingdom

Study description

The purpose of this Post-authorisation safety study (PASS) is to evaluate the effectiveness of the education material risk minimisation measures being implemented in the EU, in healthcare professionals prescribing CZP and patients who are prescribed CZP

Study status

Finalised

Contact details

Study institution contact

UCB Biopharma SPRL Personal identifiable data of lead investigator are not published here, as consent is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

UCB Biopharma SPRL Personal identifiable data of lead investigator are not published here, as consent is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/07/2016

Actual: 19/07/2016

Study start date
Planned: 01/08/2016

Actual: 01/08/2016

Data analysis start date
Planned: 31/07/2019

Date of final study report
Planned: 30/11/2019

Actual: 30/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SPRL

Study protocol

UP0038-protocol-amend-2-final-redacted.pdf (2.08 MB)

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:

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

Assessment of the effectiveness of the risk minimisation plan educational materials

Data collection methods:

Primary data collection

Main study objective:

To evaluate the effectiveness of the educational material risk minimisation measures being implemented in the EU, in healthcare professionals who are prescribing and/or administering CZP, and in patients who are prescribed CZP

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

CERTOLIZUMAB PEGOL

Medical condition to be studied

Axial spondyloarthritis

Ankylosing spondylitis

Psoriatic arthropathy

Rheumatoid arthritis

Population studied

Short description of the study population

The population for the healthcare professionals (HCP) survey was:

1. HCPs who have prescribed or monitored patients receiving treatment with CZP

2. HCPs who have not previously completed a survey regarding the risks of CZP

The population for the patient survey was:
1. Patients who were male or female and were ≥18 years of age
2. Patients who had not previously participated in any surveys about the educational tools for CZP
3. Patients who had received ≥1 prescription of CZP within the last 6 months
4. Patients who were not HCPs themselves (eg, a doctor, nurse, pharmacist)

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

295

Study design details

Outcomes

Proportion of respondents who received, were aware of, or accessed each of the CZP educational materials (Patient Alert Card and Prescriber Guide)

Data analysis plan

To evaluate healthcare providers’ knowledge of the CZP educational materials, two key assessment measures will be required: - A presentation of the percentage of HCPs who received, were aware of or accessed each of the CZP educational materials and to what extent those materials were read- A

summary of correct responses to each individual question on the understanding of CZPIn order to evaluate patients’ knowledge of the CZP educational materials program, two key assessment measures are required: - A presentation of the percentage of patients who received, were aware of, or accessed the CZP educational materials and to what extent those materials were read and understood.- A summary of correct responses to each question regarding CZP risks.

Documents

Study results

UP0038-bodytext-final-redacted.pdf (2.02 MB)

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)

Other

Data sources (types), other

Surveys will be used to assess the effectiveness of the risk minimisation methods

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