The safety and clinical effectiveness of rapid infusion with CT-P10 in patients with non-Hodgkin’s lymphoma or chronic lymphocytic leukaemia: a retrospective non-interventional post-authorisation safety study in Europe (CT-P10 rapid infusion)

First published: 10/08/2018

Last updated: 02/04/2019

Study Planned

Administrative details

EU PAS number

EUPAS25213

Study ID

29185

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

In February 2017, CT-P10 became the first biosimilar version of rituximab to be approved by the European Medicines Agency (EMA) for the treatment of rheumatic diseases and specific blood cancers including non-Hodgkin’s lymphoma (NHL) and chronic lymphocytic leukaemia (CLL). The safety profile of rituximab has been documented in numerous clinical trials, with infusion-related reactions (IRRs), thought to be related to the release of cytokines, being the most commonly reported adverse reaction. To minimise the risk of IRRs, the standard administration protocol for rituximab, specified in the summary of product characteristics, takes approximately three to four hours for the first infusion and two to three hours for subsequent infusions for oncology treatment. This standard infusion protocol places a significant burden on the healthcare system and patients and, consequently, many healthcare professionals now administer rituximab as a rapid infusion (over a period of 90 minutes or less) for second or subsequent infusions in patients who did not experience serious complications with their initial infusion(s). A number of studies have been conducted to evaluate the safety of rapid infusion of rituximab in patients with haematological malignancies and have generally shown rapid administration to be safe and well-tolerated, with low incidences of IRRs. However, there are very limited data available on the safety of rapid infusion of CT-P10. These data are important to inform future decisions by physicians and healthcare providers regarding the most appropriate and cost-effective treatment strategy. This study will address this evidence gap by collecting real world data on the safety and effectiveness of rapidly infused CT-P10 in patients with NHL and CLL in Europe.

Study status

Planned

Research institutions and networks

Institutions

Celltrion

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pier Luigi Zinzani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2018

Study start date
Planned: 01/05/2018

Date of final study report
Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion Healthcare Hungary Kft.

Study protocol

PASS PT_Celltrion RAPID_v2 0 FINAL_18APR2018.pdf (1.16 MB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To describe the incidence of infusion-related reactions (IRR) associated with rapid infusion of CT-P10 in patients with NHL or CLL on day 1 or day 2 after the index event (index event defined as the first rapid infusion of CT-P10, which must have been given as part of the second or a subsequent treatment cycle)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC02) rituximab

rituximab

Medical condition to be studied

Diffuse large B-cell lymphoma

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

300

Study design details

Outcomes

Proportion of patients who experience an IRR* on day 1 or day 2 after the index event.* An IRR is defined as any AE from a pre-defined list occurring on day 1 or day 2 after an infusion of CT-P10. IRRs, grade 3 or grade 4 IRRs, any adverse event (AE), any serious adverse event (SAE), any grade 3 or grade 4 AE, AEs as the primary cause for treatment discontinuation, overall survival (OS), progression free survival (PFS), best response, overall (complete/partial) response rate, time, NHL / CLL treatment patterns, patients' demographic, clinical, and NHL/CLL disease characteristics

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Data analysis plan

For the primary endpoint analyses, the frequency and proportion of patients receiving CT-P10 who experience IRRs on day 1 or day 2 after the index event will be presented with 95% CI. The proportional Z-test will be used to compare the IRR rate observed in this study with rates previously reported for reference rituximab in the literature.

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

Medical records in participating hospitals and medical centers

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