Retrospective Cohort Study of Certolizumab Pegol (Cimzia®) and Other Subcutaneous Anti-Tumour Necrosis Factor-Alpha Drugs in Rheumatoid Arthritis to Explore Usage Patterns and Clinical Outcomes in daily clinical practice in the United Kingdom

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/3358

EU PAS number
EUPAS3357

Study ID
3358

DARWIN EU® study
No

Study countries
United Kingdom

Study description
This is a multicentre, non-interventional, retrospective, cohort study to describe clinical patterns of use, clinical outcomes and kinetics of response of certolizumab pegol (CZP or Cimzia®) and other subcutaneous anti-tumour necrosis factor- alpha therapy (anti-TNF?)

(etanercept and adalimumab) followed up for at least one year in anti-TNF? naive rheumatoid arthritis (RA) patients in daily hospital clinical practice in the UK. The data will be useful to understand the clinical patterns of use and identify factors that influence clinical outcomes for CZP and other anti-TNF?s in routine clinical practice. The results will also be helpful for the design of prospective/pragmatic studies and help to assess the opportunities for future formal comparative analyses of CZP with other individual subcutaneous anti-TNF?s. Retrospective data contained in patient´s hospital clinical records will be collected in an anonymous manner. The retrospective observational nature of the study does not interfere with the therapeutic decision of the treating physician. The primary objective is to assess the proportion of clinical response at 52 weeks in RA patients commenced on CZP therapy.The secondary objectives are to assess the proportion and kinetics of clinical response by time up to 52 weeks for CZP and individual subcutaneous non-CZP anti-TNF? drugs, etanercept and adalimumab, combined and separately, in RA patients. Other secondary objectives are to determine if an early clinical response, and the accompanying treatment decision, at 12 weeks to CZP therapy is a predictor of long term clinical response at 52 weeks compared with a lack of clinical response at 12 weeks and compared with a 24 week clinical response for CZP. Discontinuation and switching from CZP, etanercept and adalimumab will also be evaluated.

Study status
Planned

Research institution and networks

Institutions

OXON Epidemiology
Spain
United Kingdom
First published: 06/12/2010
Last updated
15/03/2024

Institution
Non-Pharmaceutical company
Laboratory/Research/Testing facility
ENCePP partner

Guy's and St Thomas' NHS Foundation Trust
First published: 01/02/2024
Last updated
01/02/2024

Institution

London Barts and the London School of Medicine and Dentistry, London Guy's and St Thomas' NHS Foundation Trust, Cannock Cannock Chase Hospital, Christchurch Christchurch Hospital, Eastbourne Eastbourne District General Hospital

Contact details

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
19/10/2012

Study start date
Planned:
30/01/2013

Data analysis start date
Planned:
01/05/2013

Date of final study report
Planned:
30/09/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Pharma Limited

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:
Effectiveness study (incl. comparative)

Main study objective:
The primary purpose of the study is to assess the proportion of patients with DAS response, defined as a reduction from Baseline in a DAS28(ESR) score of ? 1.2 points, which is considered the minimum clinically important difference (MCID), at 52 (+/- 6) weeks in RA patients commenced on CZP therapy.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
CERTOLIZUMAB PEGOL
ETANERCEPT
ADALIMUMAB

Medical condition to be studied
Rheumatoid arthritis

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
532

Study design details

Outcomes
The primary efficacy variable is the proportion of patients with a DAS response at 52 (+/- 6) weeks. • Proportion of patients achieving a DAS response at 12 weeks and 24 weeks.• Proportion of patients achieving low disease activity.• Proportion of patients achieving remission. • Proportion of patients discontinuing the index therapy.• Proportion of patients switching from the index therapy to another biological agent (anti-TNF?, rituximab and other DMARDS).

Data analysis plan
The primary efficacy endpoint will be analysed using frequency, proportion and corresponding 95% confidence intervals.The primary endpoint will be subject to subgroup analyses investigating the effect of several baseline factors using logistic regression. Secondary efficacy endpoints will be analysed using frequency, proportion, and logistic regression, controlling by centre effect (if applicable). Sensitivity analyses will be conducted that differ in how missing data at the 52 week time point are treated.Discontinuation rates will be calculated and hazard rates will be computed by Kaplan–Meier.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Retrospective patient hospital clinical note/chart review

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