Safety and Effectiveness of Ocrelizumab under Real World Conditions: a Non-Interventional Post Authorization Safety Study in Patients Diagnosed with Relapsing or Primary Progressive Multiple Sclerosis (CONFIDENCE)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47489

EU PAS number

EUPAS22951

Study ID

47489

DARWIN EU® study

No

Study countries

☐ Germany

Study description

CONFIDENCE is a prospective, multicenter, non-interventional, long-term study collecting primary data in RMS and PPMS patients newly treated during their course of MS therapy with ocrelizumab, or selected MS DMTs (i.e., alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide), in routine clinical practice. To provide robust evidence on the safety and effectiveness profile of ocrelizumab, data from 3000 MS patients treated with ocrelizumab and 767 MS patients treated with other selected MS DMTs from approx. 185 neurological centers and practices in Germany are planned to be included.

Study status

Ongoing

Contact details

Study institution contact

Dr. Sandra Blümich

Study contact

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Primary lead investigator

Dr. Sandra Blümich

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 02/02/2018

Study start date
Planned: 30/03/2018

Actual: 03/04/2018

Date of final study report
Planned: 30/11/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hoffmann La Roche

Study protocol

ML39632_NI-PASS Confidence fv1.0_2018-01-26_Redacted.pdf(1.02 MB)

ML39632_CONFIDENCE_Protocol_V6.0_Redacted.pdf(2.37 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ML39632

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 assess the long-term safety, with special focus on the occurrence and characterization of uncommon AEs in patients with MS newly exposed to ocrelizumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OCREVUS

Medical condition to be studied

Multiple sclerosis

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

3767

Study design details

Outcomes

Incidence and type of uncommon AEs (i.e. AEs with an incidence rate of at least 0.1% to 1% 1 to 10 out of 1000 patients or less) and death with primary and

underlying causes in patients with MS newly exposed to ocrelizumab. - incidence and type of uncommon AEs and death with primary and underlying causes in patients with MS newly exposed to selected MS DMTs other than ocrelizumab -treatment success -proportion of patients with relapses - proportion of patients with CDP -time to onset of CDP and CDI -patient reported outcomes -incidence of AEs, serious infections, malignancies, mortality rate due to malignancies

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Data analysis plan

The primary endpoint will be analyzed for each combination of cohort treated with ocrelizumab, MS type and Safety Set. Frequencies of adverse events will be calculated based on MedDRA coding and presented with two-sided 95% Clopper-Pearson intervals. Analogously, the key secondary endpoint will be analyzed for the cohort treated with other DTMs. Effectiveness analyses will be conducted on each combination of cohort, MS type and Full Analysis Set. Secondary, exploratory and other endpoints will be analyzed descriptively. Depending on the endpoint, a logistic, negative binomial, linear or ANCOVA model will be fitted. Time-to-event data will be analyzed with Kaplan-Meier. Other safety analyses will be conducted analogously to the primary endpoint. For safety endpoints time adjusted analyses based on patient years will be performed. To investigate potential channeling effects, a sensitivity analysis of selected endpoints will be performed based on various time spans of patients enrolled.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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