A prospective, observational, UK study to describe patient reported quality of life in relapsing remitting multiple sclerosis patients treated with Aubagio® (teriflunomide) 14 mg in a routine clinical practice. (TeriQoL)

First published: 05/02/2019

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS27883

Study ID

27884

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is a 2 year prospective, multicentre observational UK Study to describe HRQoL and other PROs in RRMS patients treated with Aubagio® (teriflunomide) 14 mg in a routine clinical practice. The study will be conducted at approximately 20 sites in the UK and will collect data on the current status, characteristics, and management of patients who are starting treatment with Aubagio® as part of their routine medical care. The decision to treat with Aubagio® must be made prior to and independently from the proposal to enrol the patient on this study. All patients must be prescribed Aubagio® in accordance with the UK SmPC.This is an observational study with no experimental intervention. Enrolled patients will receive treatment and evaluations for their MS as determined by their treating physicians in accordance with the local standard of care. Visits will be scheduled by the treating HCP according to patient-specific needs and local clinical practice. Administration of Aubagio® and monitoring of patients according to the SmPC and safety reporting will be the sole responsibility of the treating neurologist. Patients will be followed with laboratory monitoring in a regular healthcare setting in line with locally approved label requirements and the Risk Management Plan (RMP) for Aubagio®.For purposes of this study, 6 visits are expected: study baseline (Visit 1), with follow up visits at months 3 (if part of clinical setting), 6, 12, 18 and 24. Patients will be expected to complete up to 7 questionnaires (see section 2.2) at different time points. Completing all of the questionnaires takes approximately 45 minutes. Questionnaires will be completed by the patient at the site during study visits or within 7 days before study visits (for visits V3-V6). Each questionnaire can be completed on a different day. Patient-reported outcomes, clinical outcomes and safety findings during routine clinical practice will be recorded for the entire cohort .

Study status

Ongoing

Research institutions and networks

Institutions

Royal Devon and Exeter NHS Foundation Trust

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Institution

Contact details

Study institution contact

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Study contact

claire.jones@sanofi.com

Primary lead investigator

Timothy Harrower

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/06/2018

Study start date
Actual: 16/08/2018

Data analysis start date
Actual: 16/08/2018

Date of interim report, if expected
Planned: 30/09/2020

Date of final study report
Planned: 01/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

TERIFL08182 Protocol -final Version 2.0 28032018.pdf (214.21 KB)

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

Study number: TERIFL08182

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

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

Patient reported quality of life

Main study objective:

The primary objective of this study is to describe the change in HRQoL at 2 years in patients commencing treatment with Aubagio® in routine clinical practice for RMMS.

Study drug and medical condition

Medical condition to be studied

Relapsing-remitting 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

100

Study design details

Outcomes

The primary study endpoint is the change in HRQL at month 24 compared with baseline, as measured by the MSIS-29. the secondary variables areClinical outcomesDescribe the number of relapses during the two year periodPROsFatigueAnxiety and depressionCognitionSexual DysfunctionDisease progressionTreatment satisfactiontreatment adherenceHealth economics outcomesAssessed by number of scheduled and unscheduled healthcare professional encounters and emergency visits and productivity loss

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Data analysis plan

The analysis population will include all enrolled patients who received at least one dose of study medication. All study analysis, including safety analysis, will be performed in this population. All recorded clinical observations will be analysed using descriptive statistics.Data will be summarized into counts of non-missing data, mean, standard deviation, and minimum, maximum, median, Q1, and Q3 for quantitative variables and frequency and percent for categorical data. The 95% confidence interval will be provided when necessary.Subgroup

analysis may be conducted as deemed necessary.The frequency and percentage of patients experiencing AEs, SAEs, and AESIs will be reported. The number and proportion of not serious and serious adverse events will be calculated. All non-serious and serious adverse events and the related information will be presented in individual data listing tables as well.

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

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