An Observational, Cross-Sectional Survey to Assess PML Risk Awareness and Understanding from Patients' Perspective and Effectiveness of the Tysabri (Natalizumab) Patient Alert Card in the UK (T-PAC)

First published: 12/09/2023

Last updated: 12/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS106690

Study ID

106698

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Study examining patients reponses to the issued patient alert card for Tysabri via the UK MS Register.

Study status

Finalised

Research institutions and networks

Institutions

UK MS Register

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Swansea University

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 17/04/2023

Actual: 18/04/2023

Study start date

Planned: 14/05/2023

Actual: 15/05/2023

Data analysis start date

Planned: 24/06/2023

Actual: 24/06/2023

Date of interim report, if expected

Planned: 28/09/2023

Actual: 28/09/2023

Date of final study report

Planned: 30/11/2023

Actual: 11/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

GB-TYS-12163 Protocol V2 Final 01Dec2022 Redacted.pdf (2.01 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)

Other study registration identification numbers and links

GB-TYS-12163

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

Questionnaire on Patient Alert Card recall

Main study objective:

This study’s research questions are to assess:

• What is the patient’s overall awareness of PML?

• How effective is the Tysabri (natalizumab) PAC in educating patients to ensure they are aware of the risk of PML whilst receiving Tysabri treatment (and for up to 6 months after stopping Tysabri), and exercise vigilance regarding its development?

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

TYSABRI

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

NATALIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG03) natalizumab

natalizumab

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

700

Study design details

Outcomes

The primary objectives of the study are to assess the following in patients treated with Tysabri (natalizumab) in the UK:

• The level of PML risk awareness

• The effectiveness of the Tysabri (natalizumab) PAC in conveying the risk of PML to patients

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Data analysis plan

Descriptive analyses of UK MS Register patients will be performed by UK MS Register to characterise the study population (RRMS patients receiving Tysabri IV or SC). Summary statistics such as mean and standard deviation for continuous variables and frequency table for categorical variables will be provided. Data analyses will generally be descriptive and will be detailed in the SAP. Patient understanding of the PAC and the symptoms of PML will be determined for Tysabri IV and Tysabri SC patients. The proportion of patients who have good, fair, and poor knowledge of PML symptoms and risk factors in determining the knowledge will be assessed. Specifically, PML knowledge will be stratified based on receipt of HCP- and patient-related metrics (provided in the SAP) to determine the effectiveness of the PAC in conveying knowledge of PML to patients.

Documents

Study report

GB-TYS-12163 Abstract V2 Final 11Jul2024 Redacted[69].pdf (241 KB)

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 source(s), other

UK MS Register (UKMSR)

Data sources (types)

Other

Data sources (types), other

Population from UKMSR that have declared that they are currently taking Tysabri or had been taking it within 6 months of questionnaire deployment.

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