OPTIMISE:MS A Prospective, Real World Pharmacovigilance Study in Multiple Sclerosis

First published: 10/11/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44060

EU PAS number

EUPAS44059

Study ID

44060

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This pragmatic, prospective observational cohort study is planned to run for 7 years to estimate the frequency of serious adverse events with real world DMT use in routine clinical practice in the UK. It is a non-interventional cohort study. The study will recruit people with MS on treatment from major MS care clinics across the country, as well as those starting, switching or potentially eligible for treatment, but who are not currently taking DMT. This study will provide – for the first time - an estimate of overall rates of serious adverse events associated with DMT (including multiple sclerosis relapses or opportunistic infections) in the UK population with MS. It will facilitate a way of exploring related questions regarding the relative benefits vs risks of treatment and the influence of prior treatments on adverse events.

Study status

Ongoing

Research institutions and networks

Institutions

Imperial College London

United Kingdom

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Institution | Educational Institution

Royal London Hospital London, John Radcliffe Hospital Oxford, Frimley Park Hospital Surrey, Nottingham University Hospitals NHS Trust Nottingham, Salford Royal NHS Foundation Trust Great Manchester, Greater Glasgow and Clyde Scotland, Plymouth Hospital NHS Trust Plymouth, Southend University Hospital NHS Foundation Trust Essex, St Georges Hospital London, University Hospitals Bristol NHS Foundation Trust Bristol

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Aleisha Miller

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/07/2018

Actual: 25/07/2018

Study start date
Planned: 28/04/2019

Actual: 28/04/2019

Data analysis start date
Planned: 27/08/2019

Actual: 27/08/2019

Date of final study report
Planned: 12/12/2026

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Biogen, Merck, Bristol Myers Squibbs

Study protocol

OPTIMISE_PROTOCOL_v6.0_12_APR_2021_CLEAN.pdf(1 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

IRAS: 252793

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

To characterize the incidence and compare the risk of serious adverse events in people with MS treated with DMD (comparators will be an untreated cohort, and a cohort treated with first line injectable DMD). A serious adverse event in this

context is an adverse event resulting in death, requiring in-patient treatment or prolongation of existing in-patient treatment or hospitalisation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

4000

Study design details

Outcomes

Primary endpoints to be examined according to treatment type, duration and switching include: ● Any SAE (any infection requiring hospitalization, any opportunistic infection, any other SAE, any relapse, death, MeDRA coded), Secondary endpoints for exploratory objectives include: Outcomes associated with sequential therapies with multiple DMT Abnormally low total blood lymphocyte count stratified by grade of lymphopaenia Abnormally increased liver function tests stratified by grade of abnormal liver function Disability progression New MRI lesion activity Occurrence of pregnancy and outcomes of pregnancy

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Data analysis plan

The total number of safety events (SAEs) for DMTs (overall and by individual DMTs) will be presented per 100 person years. Both event rates (multiple events per individual) and incidence will be examined. Continuing quality assessment of the database will be performed. Active interrogation of data collected from sites (via regular audit of a proportion of records) will enable early detection of inconsistent and/or erroneous data, allowing corrections to be made prior to any analysis. Inconsistent data will be defined on an individual patient level (where records are selected for audit), e.g. where clinical records are intrinsically inconsistent (e.g. large fluctuations in EDSS recorded with no relapses recorded, large fluctuations in laboratory values without clinical or treatment correlates). In sites where inconsistent data is detected, further records will be interrogated to further evaluate if any systematic error is present.

Data management

Data sources

Data sources (types)

Disease registry

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