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A descriptive study of Relapsing-Remitting Multiple Sclerosis (RRMS) treated with first disease modifying therapies (DMTs) in current UK clinical practice: patterns of clinical decision making and the patient experience of relapse

Submission date
24/04/2012

Recruitment status
No longer recruiting

Registration date
26/07/2012

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a research study being carried out at six hospitals in the UK. It will look back over 3 years at how well patients with multiple sclerosis (MS) respond to medicines known as disease modifying therapies (DMTs), which are used to treat MS. We are also looking at the effect a relapse has on the everyday life of a person with MS. DMTs have all been tested in clinical trials and approved for treating patients, but in this study we want to get more information about the experience of patients using them. This study is designed to increase understanding of how well DMTs work as initial treatments for Relapsing Remitting MS (RRMS), in patients real-world setting rather than in formal clinical trials.
We understand the progression and accumulation of disability in the later stages of MS quite well, but the physical, psychological and financial impact of relapses in early disease is less clear and potentially underestimated. Differing perceptions between physicians and patients on the nature and severity of a relapse may contribute to this.

Who can participate?
Patients with a diagnosis of RRMS, and who started a DMT for the first time in 2008, will be eligible to participate.

What does the study involve?
Patients will be identified at 6 UK centres and will be invited to participate by post. They will be sent an information sheet, and details of a person to contact if they require further information. Once the consent has been returned (by post), the participant will be enrolled in the study and will receive another package by post. Included in this pack are a retrospective questionnaire to provide information on the participants experience of their last relapse, and three short questionnaires to inform us of their current health status. Once this is returned, the participant will have completed their role in study.

We will also look at the medical records of those who allow us to do so. We will look at the number of relapses that occur in the 3 years after the first prescription of DMTs, any changes in medication, and the number of clinic visits needed during this time.

What are the possible benefits and risks of participating?
There are no direct risks or benefits to the participant in this study as there will be no change in patient care. The benefit is adding to the literature in this area to inform clinical and policy decisions about patient care.

Where is the study run from?
This study is coordinated independently by pH Associates. The six centres taking part will be: The Royal Victoria Infirmary - Newcastle, Queens Hospital - Romford, Charing Cross Hospital - London, Leicester General Infirmary - Leicester, Norfolk and Norwich University Hospital Norwich, and Morristen Hospital - Swansea.

When is study starting and how long is it expected to run for?
May 2012 to December 2012.

Who is funding the study?
Novartis Pharmaceuticals UK Ltd (UK)

Who is the main contact?
Heather Davies
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CFTY720DGB02

Study information

Scientific Title
A multi-centre observational study of relapsing-remitting multiple sclerosis (RRMS) treated with first disease modifying therapies (DMTs) in current UK clinical practice: patterns of clinical decision making and the patient experience of relapse

Study objectives
To describe the number of documented relapses experienced by people with MS (PwMS) in the first 3 years following DMT initiation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes - London-Bromley, approved 4th April 2012, ref: 12 LO 0248

Study design
Multi-centre observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Multiple Sclerosis

Interventions
1. Retrospective questionnaire on the patients experience of the last relapse
2. Three short health questionnaires
3. Review of medical records over 3 years from the first prescription of a disease-modifying treatment for relapsing-remitting multiple sclerosis

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To describe the number of documented relapses experienced by patients with MS in the first 3 years following DMT initiation

Key secondary outcome(s))
1. To describe the number of documented relapses experienced by patients with MS in the 3 years following DMT initiation by severity
2. To describe the DMT prescribing patterns in the first three years following DMT initiation
3. To compare clinician-documented and patient-reported relapse symptoms

4. To describe the change in patient contact with health care professionals resulting from relapse
5. To describe the financial impact of a relapse on patients with MS
6. To describe the impact of a relapse on patients attitudes to DMT

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Patients with RRMS by 2005 MacDonald criteria
2. Patients initiated on DMT for the first time after 1 January 2008 and at least 36 months before date of screening for inclusion
3. Patients who consent to complete the questionnaire and for their medical records to be reviewed for the purposes of healthcare research
4. Patients who are able to complete the study questionnaires or have a carer who is able and willing to record the patients responses to the study questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who are unwilling or unable to provide patient consent
2. Patients who are unable to complete the study questionnaires themselves and have no appropriate carer able and willing to assist them

Date of first enrolment
01/06/2012

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Novartis Pharmaceuticals UK Ltd
Frimley
United Kingdom
GU16 7SR

Sponsor information

Organisation
Novartis Pharmaceuticals Ltd (UK)

ROR
https://ror.org/039s6n838

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals UK Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration