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by Roche

Multiple Sclerosis (MS)

A study to evaluate specific unmet needs in the current clinical practice of multiple sclerosis

Evaluation of specific unmet needs in the current clinical practice of multiple sclerosis: characterization of different profiles of relapsing multiple sclerosis patients defined by disease activity and patient-reported outcomes (Profile RMS)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Countries	ML39348

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

Multiple sclerosis (MS) is an incurable condition where the immune system attacks myelin, the protective layer around nerve fibers. This makes it difficult for the brain to send signals to the rest of the body. Common symptoms include tiredness, vision problems, and problems with walking or balance. A majority of people experience a form of MS called relapsing-remitting MS (RRMS) which is characterised by a pattern of clearly defined relapses that are divided by symptom-free periods. If left untreated RRMS will transition through an intermediate state of relapsing secondary progressive MS (rSPMS) into secondary progressive MS (SPMS), which is characterised by increased disability in addition to relapses. Several disease-modifying treatments (DMTs) have been shown to reduce the number of relapses, slow the progression of the disease and thus delay disability. However, in spite of this there are still several critical questions remaining: What constitutes a truly effective medication in MS management? What are the actual unmet needs of MS medications? The aims of this study are:

- To describe the different patient sub-groups (profiles) seen in clinical practice and to identify the unmet medical needs in the current care of relapsing multiple sclerosis (RMS) (RRMS and rSPMS). For this purpose, five specific subgroups of RMS (RRMS and rSPMS) patients with significant unmet needs will be prospectively monitored under real-life conditions to assess disease- and patient-related outcomes
- To study MS activity using various assessment parameters such as magnetic resonance imaging (MRI), clinical assessments, patient-reported treatment satisfaction, disability, MS symptoms, adapted clinical global impression (CGI) scale as reported by the patient and the physician
- To find out the nature, frequency, and severity of adverse events (AEs) and serious adverse events (SAEs)
- To study the nature, frequency, and severity of adverse drug reactions (ADRs) and serious adverse drug reactions (SADRs)

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ML39348
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	**>= 18 years**	**No**

Who can participate? People over 18 years of age with RMS (RRMS and rSPMS)

What does the study involve?
Participants may be asked to be in the study for up to 12 months. This includes:

A screening period where participants will be assessed for eligibility to participate in the study and further into the following subgroups:

Subgroup 1 will include participants with MS who have been on DMT for the past 12 months.

Subgroup 2 will include participants with MS who have experienced significant side effects with DMTs.

Subgroup 3 will include participants with MS who have low treatment satisfaction.

Subgroup 4 will include participants with MS who have never received any treatment for the disease.

Subgroup 5 will include participants with MS who are without treatment currently but had been previously treated with a DMT.

During the observation period three visits are recorded by the study doctor in a standardised form either on paper or electronically. The first visit will be the baseline and the second and the third observation visits should take place around 6 and 12 months (±2 weeks) after the baseline visit.

During clinic visits, participants will be assessed for various parameters such as progression of the disease, treatment satisfaction, extent of disability, frequency of relapses, overall disease status, and so forth. Assessments will be made using patient questionnaires, lab tests, MRI scans, etc.

What are the possible benefits and risks of participating?

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Participants will not receive any benefit from participating in this study, but the information that is learned from this study may help researchers and doctors to learn more about MS in general and other people who have a similar medical condition may benefit from the results of such research in the future. There are no risks from participating in the study.

Where is the study run from?
Roche Pharma AG (Germany)

When is the study starting and how long is it expected to run for?
November 2016 to September 2023

Who is funding the study?
Roche Pharma AG (Germany)

Who is the main contact?
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