ForPatients
by Roche

Multiple Sclerosis (MS)

A study to investigate the concordance of smartphone-based self-monitoring, imaging, and blood-based biomarkers with clinical disability in participants with multiple sclerosis (MS)

A prospective investigation of the concordance of smartphone-based self-monitoring, imaging, and blood-based biomarkers with clinical disability in patients with multiple sclerosis within the TONiC program

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	MN43238

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

Trial Summary:

The aim of this study is to evaluate the feasibility of using the Floodlight multiple sclerosis (FL MS) application to characterize neurological impairment in patients with MS.

F. Hoffmann-La Roche (USA)
Sponsor

MN43238
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	>=18 years	No

Multiple sclerosis (MS) is a lifelong condition that affects the brain and nerves. Common symptoms include tiredness, vision problems and problems with walking or balance. The main purpose of the study is to assess how the Floodlight (FL) MS App helps and/or improves the portrayal of neurological (nervous system) disability in patients with MS. FL MS is a smartphone application that informs users of various conversations and health care provider decisions by collecting information on patient function in between clinic visits. This app also helps collect data regarding patient symptoms and neurological function such as gait, balance while moving, hand function and cognition (mental abilities such as learning, thinking, problem-solving etc) over a period of time. The study will look at:

- The ease of using the FL MS App to describe domain-specific (cognition, hand function, gait and balance) neurological disabilities
- The ease of using the FL MS App to describe the overall neurological disability
- The ease of using the FL MS App to describe the course of the disease
- The ease of using the FL MS App to describe a relapse (worsening of the disease after a temporary improvement)
- The ease of using the FL MS App to describe participant and disease characteristics collected using patient-reported outcome measures (PROMs) - a questionnaire to track daily mood, physical abilities and symptoms
- The participant's user experience with the FL MS App which helps them to report outcome measures digitally regularly and also the risks they feel are associated with it
- The ease with which the risk score obtained from the FL MS App can be used to predict the progression of disability
- The features of participants with slow and fast disease progression according to the outcome measures and PROMs
- The convenience of using the FL MS App to describe biomarkers (signs of certain medical conditions that can be measured) of neurological impairment and the course of the disease

Who can participate?
Patients with MS who are over 18 years of age and have a smartphone

What does the study involve?
Participants may be asked to be in the study for up to 4 years. Participants will be assessed for eligibility to participate in the study and their ability to use a smartphone. Eligible participants will be given access to the FL MS App and will be enrolled in the study the same day. There will be a run-in period of 8 weeks to help participants learn how to use the FL MS App, followed by an observational period where participants will be followed up for at least 3 years with one check-up at the clinic every year. Participants who have been selected for biomarker assessments will be followed up for one additional year (a total of 4 years).

The FL MS App will prompt the participants to perform various tests to assess cognition, hand function (drawing a shape test and pinching test) and gait and balance (2-minute walk test and U-turn test). The participants can also record any other symptoms in a journal within FL MS. Participants can also provide feedback, following a clinic visit, through the app using a questionnaire. During each annual clinic visit information regarding disability, performance, PROMs, clinical MS data such as relapses and changes in treatment will be collected.

What are the possible benefits and risks of participating?
There is no direct medical benefit from being in this study, but participants will be able to see the information recorded on the App. The information gained 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?
F. Hoffmann-La Roche (USA)

When is the study starting and how long is it expected to run for?
October 2021 to September 2027

Who is funding the study?
F. Hoffmann-La Roche (USA)

Who is the main contact?
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