ELIOS - Investigational Biomarkers to Track Disease Modification in Active RRMS

Last Update: Jun 05, 2025
Exploratory Evaluation of Novel Investigational Eye Movement Biomarkers to Track Ofatumumab Treatment Response in Canadian Patients With Active Relapsing-Remitting Multiple Sclerosis (ELIOS)
ClinicalTrials.gov Identifier:
NCT06733922
Novartis Reference Number:COMB157GCA05
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The exploratory ELIOS study aims to assess the value of novel investigational Eye Movement Biomarkers (EMBs) in tracking disease-related changes among a real-world cohort of Canadian patients with active RRMS, within the context of disease-modifying treatment (i.e., ofatumumab). To that end, the study will use the patented investigational, Eye Tracking Neurological Assessment (ETNA-ProgMS) SaMD (v1.0.11 or later), which has not yet received Health Canada approval, to reliably and accurately track eye movements with precision.

Condition
Relapsing Remitting Multiple Sclerosis (RRMS)
Phase
Phase4
Overall Status
Recruiting
Number of Participants
224
Start Date
Nov 27, 2024
Completion Date
Nov 30, 2027
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Device

ETNATM-ProgMS

To that end, the study will use the patented investigational ETNATM-ProgMS SaMD (v1.0.11 or later), which has not yet received Health Canada approval, to reliably and accurately track eye movements with precision. Of note, investigational versions of this SaMD are used for the purpose of clinical research only and will not be commercialized.

Eligibility Criteria

Inclusion criteria

Patients eligible for inclusion in the study must fulfill all of the following criteria:

1. Adult patients who are prescribed ofatumumab as part of routine clinical care as per the PM but who have not yet received their first dose. The decision to prescribe ofatumumab must be made prior to and independent of study participation.
2. Patients or their legally authorized representatives who sign the Institutional Review Boards/Independent Ethics Committee (IRB/IEC)-approved informed consent form.
3. Patients who meet the EDSS score range of 0 up to 7 at the time of screening and enrollment for ofatumumab treatment.
4. Patients with a diagnosis of active RRMS according to the 2017 Revised McDonald criteria2.
5. Patients who can provide blood samples.
6. Patients who can understand written and spoken Canadian English or French.
7. Patients who have sufficient corrected visual acuity to allow for accurate reading of the on-screen visual task instructions, in the judgement of the Investigator. If a relapse temporarily affects a patient's corrected visual acuity, the Baseline Visit may be postponed until the patient can accurately read the on-screen visual task instructions, if deemed acceptable by the Investigator and the patient.
8. Patients with a confirmed diagnosis of MS with no signs of progressive increase in physical disability independent of relapse activity within the past six months, as assessed by a physician.

Exclusion criteria

In order to ensure that the study population will be representative of all eligible patients, no additional exclusions may be applied by the Investigator. Patients meeting any of the following criteria are not eligible for inclusion in this study:

1. Patients with primary progressive MS, secondary progressive MS without disease activity, clinically isolated syndrome, or radiologically isolated syndrome.
2. Any disease or condition that could interfere with participation in the study according to the study protocol, or with the ability of the patients to cooperate and comply with the study procedures.
3. Pregnant or nursing (lactating) women.
4. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using effective methods of contraception while taking ofatumumab and for six months after stopping medication. Effective contraception methods include:

* Total abstinence (when this is in line with the preferred and usual lifestyle of the participant). Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception
* Female sterilization (have had surgical bilateral oophorectomy with or without hysterectomy), total hysterectomy, or tubal ligation at least six weeks prior to enrollment. In case of oophorectomy alone, the

reproductive status of the woman must be confirmed by follow-up hormone level assessment
* Male sterilization at least six months prior to enrollment. For female participants on the study, the vasectomized male partner should be the sole partner for that participant
* Use of oral (estrogen and progesterone), injected or implanted hormonal methods of contraception, placement of an intrauterine device or intrauterine system, or other forms of hormonal contraception that have comparable efficacy (failure rate \<1%) such as hormone vaginal ring or transdermal hormone contraception
* Use of barrier methods of contraception (male or female condom, occlusive cap, diaphragm or cervical/vault caps)
* In case of use of hormonal contraception women participants should have been stable on the same method for a minimum of three months before taking study treatment.
* If local regulations are more stringent than the contraception methods listed above, local regulations apply and will be described in the ICF.
* Women are considered post-menopausal if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g., age-appropriate history of vasomotor symptoms). Women participants are considered not of child-bearing potential if they are post-menopausal or have had bilateral tubal ligation, surgical bilateral oophorectomy (with or without hysterectomy), total hysterectomy or bilateral salpingectomy at least six weeks prior to first dose of study treatment on study. In the case of oophorectomy alone, a woman is not considered to be of child-bearing potential only when the reproductive status has been confirmed by follow-up hormone level assessment.
5. Patients with hypersensitivity to ofatumumab or to any ingredient in the formulation, active hepatitis B virus, progressive multifocal leukoencephalopathy (PML), severe active infections, in a severely immunocompromised state or with known active malignancies.
6. Patients with an active chronic disease (or stable but treated with immune therapy) of the immune system other than MS (e.g., rheumatoid arthritis, scleroderma, Sjögren's syndrome, Crohn's disease, ulcerative colitis, etc.) or with immunodeficiency syndrome (hereditary immune deficiency, drug-induced immune deficiency).
7. Patients who are using other investigational drugs within 30 days prior to or at the Baseline Visit, or within a period corresponding to five elimination half-lives, whichever is longer, or who are using other investigational drugs for which the expected pharmacodynamic effect has not returned to baseline.
8. Contraindication or inability to undergo regular testing (e.g., MRI, blood tests) as per standard of care.
9. Patients who have been treated with cladribine or with alemtuzumab at any time within the 12 months prior to the Baseline Visit.
10. Patients who have had any prior exposure to anti-CD20 B-cell therapy (i.e., ocrelizumab, ofatumumab) or natalizumab.
11. Medical history or evidence of health issues that, in the opinion of the Investigator, may affect movements and oculomotor control.

Canada

Novartis Investigative Site

Recruiting

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Recruiting

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06733922*

List of links present in page

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