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Efficacy of Ofatumumab on Microglia in Patients with Relapsing Forms of Multiple Sclerosis: Study Design

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Abstract Text:

Background:

Ofatumumab, an FDA approved fully-human anti-CD20 monoclonal antibody, is indicated for the treatment of relapsing forms of multiple sclerosis (RMS) following the results from the ASCLEPIOS trials. However, the potential impact of ofatumumab on microglial activation in MS is unknown.

Objectives:

Here we present the design of a study aimed to determine the effect of ofatumumab on microglial activation using [F-18]PBR06-positron emission tomography (PET) in RMS patients.

Methods:

An open-label, observational, prospective, 9-month study will be conducted in active RMS patients (aged 18–60 years), with evidence of clinical and/or MRI disease activity (Lublin 2014 criteria) and EDSS 0 to 5.5. Patients will undergo PET and other procedures at baseline and at days 5, 28, 90 and 270 after initiating of atumumab. The primary objective is to determine the effect of of atumumab on microglial activation over 9 months. Secondary objectives are time course of effect of of atumumab on microglial activation and its relationship with peripheral B-cell depletion, serum neurofilament light chain and glial-fibrillary acid protein levels and relationship of PET changes following of atumumab initiation with 3T MRI changes and clinical parameters.

Results:

This is a single-center study in the United States consisting of 10 patients with active RMS. The first patient first visit occurred in October 2020, and the expected study completion is in Q4 2021. The detailed study design will be presented at the congress.

Conclusions:

This is the first study to evaluate the effect of ofatumumab on microglial activation and its relationship with serum markers of neurodegeneration and reactive astroglia in RMS patients.

Title:

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Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:
Yes

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Any relevant financial relationships? Yes

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