CELLO: A Phase IV, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Assessing Efficacy of Ocrelizumab in Radiologically Isolated Syndrome

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OBJECTIVE

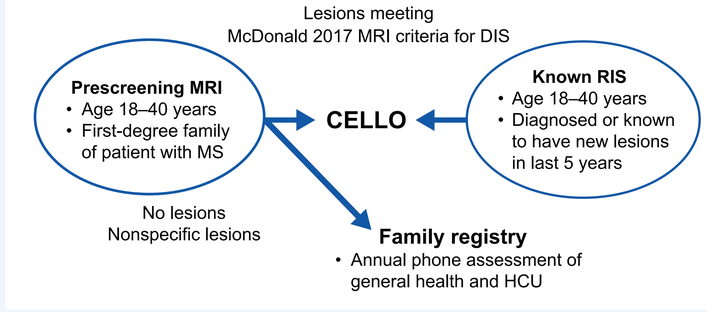
To report the study design of CELLO, a Phase IV, multicenter, randomized, double-blind, placebo-controlled study (NCT04877457), which will assess the efficacy of ocrelizumab (OCR) in delaying development of new radiological or clinical evidence of multiple sclerosis (MS) in patients with radiologically isolated syndrome (RIS)

Patients with RIS exhibit central nervous system lesions, brain atrophy, cognitive impairment and intrathecal inflammation; at least half will develop MS[1]

High-quality data, including immunologic biomarkers, to stratify risk and guide treatment decisions are lacking

Early intervention with OCR may impact the disease course and improve long-term outcomes

Figure 2. Recruitment Strategies for CELLO



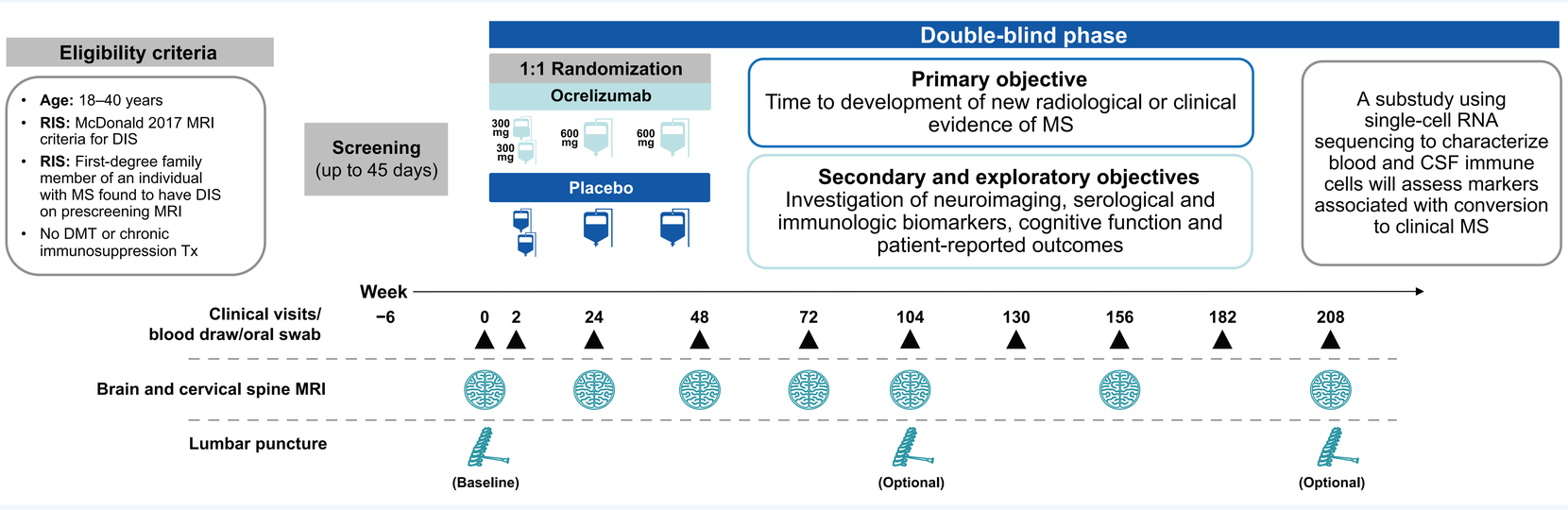
DIS, dissemination (of lesions) in space; HCU, healthcare utilization; MS, multiple sclerosis; RIS, radiologically isolated syndrome.

Table. Preplanned Biomarker Analysis for CELLO

	CSF	Blood	Oral swab
Single-cell RNA sequencing	✓	✓	
Immunophenotyping (flow cytometry)	✓	✓	
Soluble biomarker analysis	✓	✓	
DNA		✓	
Microbiome			Future

CSF, cerebrospinal fluid.

Figure 1. Study Design for CELLO



CSF, cerebrospinal fluid; DIS, dissemination (of lesions) in space; DMT, disease-modifying therapy; RIS, radiologically isolated syndrome; Tx, treatment.

CONCLUSION

- This study aims to improve the understanding of B-cell biology in early disease pathophysiology, characterize the emergence of central nervous system autoimmunity and provide evidence to support treatment initiation at the earliest stage of MS

REFERENCE

1. Lebrun-Frenay C, et al. *Ann Neurol* 2020;88:407–417.

DISCLOSURES

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