National Autonomous University of Mexico
Biomedical Research Institute

Towards the Improvement of the Treatment of Acute Relapses in Multiple Sclerosis: A Randomized Double-blind, Non-inferiority Controlled Trial Comparing Intranasal Versus Intravenous Methylprednisolone

PROTOCOL SUMMARY

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Brief Project Title: Evaluation of the efficacy and safety of intranasal methylprednisolone for the treatment of relapses in relapsing-remitting multiple sclerosis patients.

STRUCTURED SUMMARY

Introduction. Multiple Sclerosis (MS) is an autoimmune, inflammatory, demyelinating, and neurodegenerative disease of the central nervous system (CNS) that affects approximately 2.5 million people worldwide and is the most important cause of non-traumatic neurological disability in young adults. In Mexico, the prevalence of MS has increased from 5 to 13 cases per 100,000 inhabitants. MS requires acute treatment when relapse symptoms occur, otherwise, the patient has a very high risk of remaining with some disability, and even accumulating them. Among the current specific treatments for these relapses is intravenous (IV) methylprednisolone (MP), which is the standard treatment. In this work, we propose the intranasal (IN) route as an alternative to IV administration of MP to treat relapses in patients with relapsing-remitting multiple sclerosis (RRMS).

Problem Statement. MS requires acute treatment when symptoms or relapses occur. Our working group has shown that the IN-administration route is more effective for the delivery of glucocorticoids to the CNS, and a better treatment to control neuroinflammation in different neuropathologies in preclinical trials. This suggests that IN administration of methylprednisolone could be at least as effective as IV administration in treating neuroinflammation in patients with MS. Here we propose the study of the administration of methylprednisolone by the IN versus the IV route to evaluate its effect in patients with RRMS.

Purpose. To evaluate the efficacy, tolerability, and safety of methylprednisolone administered intranasally compared with intravenously in the recovery of patients with RRMS relapses.

Hypothesis. Intranasal administration of 1 g of methylprednisolone is at least as effective and safe as the same dose administered intravenously in the recovery and reversal of neurological symptoms caused by relapses in patients with RRMS.

Methodology. This is a prospective, comparative, double-blind, randomized, placebo-controlled study, in accordance with the principles established by the Declaration of Helsinki, including informed consent. Patients from the Instituto Nacional de Neurología y Neurocirugía with a diagnosis of RRMS who are experiencing a relapse will be included.

The recruited patients will be organized into two paired groups of 40 patients. Group 1 will receive 1g methylprednisolone IV and group 2 will receive 1g methylprednisolone IN. Clinical symptoms will be measured with EDSS and quality of life with the Barthel scale; The results of the serum concentration of MP and inflammatory markers will be collected. Adverse effects in each group will also be identified and quantified.

Keywords: Relapsing-remitting multiple sclerosis, Methylprednisolone, Intranasal treatment.