(W04) MONTHLY PULSE ADRENOCORTICOTROPIN HORMONE VERSUS METHYLpredNISOLONE FOR MULTIPLE SCHLEROSIS TREATMENT
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**Background:** The pathogenic mechanisms in multiple sclerosis (MS) involve inflammation, demyelination, and axonal damage. A commonly used treatment for worsening MS, among very few others, is pulse methylprednisolone (MP). While readily available, MP treatment is associated with many side effects and is not always well tolerated. Adrenocorticotropic hormone (ACTH; Acthar Gel) is a US Food and Drug Administration–approved medication for the treatment of MS relapses. However, no information is available on long-term or pulse-therapy use of ACTH for MS. The USC MS Comprehensive Care Center is initiating a study designed as a 12-month pilot, investigator-initiated, single-center, randomized, prospective, examiner-blinded, treatment trial to evaluate the efficacy and safety of monthly intramuscular (IM) ACTH injections, as compared with monthly intravenous (IV) MP infusions, as an add-on therapy in patients with MS receiving regular interferon beta (IFNβ) treatment.

**Objectives:** To determine whether monthly IM administration of ACTH, when added to IFNβ, shows promise as an alternative treatment option for control of MS disease activity, measured as annualized relapse rate (primary outcome). **Secondary clinical Objectives:** To determine whether ACTH improves Multiple Sclerosis Functional Composite (MSFC), Expanded Disability Status Scale (EDSS) score, Multiple Sclerosis Quality of Life (MSQOL) and induces regulatory immune activity and, if so, how these compare with effects of MP. **Methods:** The target patient population consists of 24 subjects, 12 in each treatment arm (Acthar Gel vs. MP), matched for age and sex. Subjects must be diagnosed with definite MS and have experienced worsening in their condition, as defined by at least 1 MS relapse and/or new T2 or gadolinium-enhancing lesion on magnetic resonance imaging (MRI) within the last year while on stable interferon therapy. Subjects will be administered either monthly IM Acthar Gel or IV MP for 12 months, and will be monitored for the study outcomes and side effects. **Results:** The study is currently open for enrollment. The investigational new drug application has been submitted and the exemption has been granted; USC institutional review board approval has been obtained. **Conclusions:** The information gained from this study is critical to establish the feasibility of ACTH use as a long-term pulse treatment option for MS.

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