**EFFICACY OF VITAMIN D3 AS ADD-ON THERAPY IN PATIENTS WITH RELAPSING–REMITTING MULTIPLE SCLEROSIS RECEIVING SUBCUTANEOUS INTERFERON BETA-1A: A PLANNED, PHASE II, MULTICENTRE, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL**

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Background/objective: Small preliminary studies of vitamin D supplementation in multiple sclerosis (MS) reported positive immunomodulatory effects, and reduced relapse rates and gadolinium-enhancing lesions. SOLAR will evaluate the efficacy (number of relapses and new T1/T2 lesions), safety and tolerability of vitamin D3 (cholecalciferol) versus placebo add-on therapy in patients with relapsing¨Cremitting MS (RRMS) receiving subcutaneous (sc) interferon (IFN) beta-1a.

Methods: SOLAR will be a multicentre, double-blind, randomized, placebo-controlled, 96-week trial (EMR 200136-532; planned recruitment: n=348) in patients (aged 18¨C50 years) from 12 European countries, with active RRMS and an Expanded Disability Status Scale score 4.0, receiving IFN beta-1a, 44 mcg sc three times weekly (tiw). Patients with 25-hydroxy-vitamin D plasma levels <150 nmol/L (n=348) will be randomized 1:1 to cholecalciferol add-on therapy (7000 IU daily, weeks 1¨C4; 14 000 IU daily, weeks 5C96) or placebo; patients with plasma levels 150 nmol/L will receive IFN beta-1a, 44 mcg sc tiw, only. SOLAR is 80% powered to detect a 16% difference in the proportion of relapse-free patients.

Results: The combined primary endpoint will comprise magnetic resonance imaging (MRI) and clinical variables: change from baseline in mean number of gadolinium-enhancing lesions at week 48 and proportion of relapse-free patients at week 96.

Conclusion: SOLAR will be the first large, placebo-controlled international study to assess vitamin D3 as add-on therapy to sc IFN beta-1a in patients with RRMS, using clinical and MRI outcomes.

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