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Identificación del proyecto

Reversión con calcifediol de la deficiencia de vitamina D en pacientes con hipertensión arterial pulmonar (EXPTE. ICI23/00001)

Descripción del proyecto

Pulmonary arterial hypertension (PAH) is a heterogeneous pathophysiological condition characterized by progressive pulmonary vascular narrowing that ultimately results in right-sided heart failure and eventually death or lung transplantation. The effectiveness of current pharmacological treatments is suboptimal and a large proportion of patients still had events or died despite receiving combination therapy. Vitamin D deficiency has been found to be much more frequent in PAH patients than in the general population or even compared to patients with other severe cardiovascular diseases. Moreover, vitamin D deficiency has a negative prognostic impact in PAH. Animal studies support that vitamin D deficiency worsens PAH. We hypothesize that in patients with PAH and vitamin D deficiency, restoration of vitamin D status with calcifediol improves their symptomatology and prognosis. Design: Multicenter clinical trial with the participation of 9 hospitals, placebo-controlled, randomized (1:1 ratio), in two parallel groups (without crossover), triple blind, and add-on on existing treatments (add-on). It will include at least 102 subjects (51 in the calcifediol group and 51 in the placebo group) followed for 24 weeks of treatment. Inclusion criteria: Patients of both sexes (18-75 years) with hemodynamic diagnosis of PAH and severe vitamin D deficiency (25-OHvitD \leq 12 ng/ml) and without previous diagnosis of osteoporosis or osteomalacia. Treatments: 1) Calcifediol Hydroferol® 0.266 mg once a week for the first 12 weeks and once every two weeks for the following 12 weeks. 2) Placebo. Main objective: A composite endpoint of clinical improvement without clinical worsening at week 24. Restoration of vitamin D status is an unexpensive measure, very easily implantable and that could improve the evolution of the disease as well as other aspects such as bone or immune health and that has few side effects.

Financiación

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