

REPLY: Pauling, et al., Efficacy and Safety of Selexipag in Adults With Raynaud's Phenomenon Secondary to Systemic Sclerosis: A Randomized, Placebo-Controlled, Phase II Study. Arthritis Rheumatol 2017;69(12):2370-2379.

ar-18-0060

Dear Sir

Pauling et al highlight some of the limitations of using the Raynaud's Condition Score (RCS) in clinical trials of Raynaud's phenomenon and the need for better patient reported outcome measures. They have explored this in a survey of patients with systemic sclerosis who completed the RCS and although the number of cases in the survey is small, and possibly not representative of a clinical trial population, the points raised are interesting.

We acknowledge the difficulties of undertaking clinical trials in Raynaud's phenomenon. Our study was designed to minimise these problems. For example, in our study RCS was not the primary endpoint and this was due to concerns from previous trials. Additionally, we pioneered an e-diary to facilitate and standardise data collection, with which patients were highly compliant and incorporated a 2-4 week single blind placebo period to confirm attack frequency. Although we accept Pauling et al's point that lifestyle adjustments may mitigate the impact of Raynaud's phenomenon, this should have been balanced by randomisation and patient education.

The challenges of clinical trials in Raynaud's phenomenon remain, and in addition to developing better patient reported outcomes, it would also be helpful to optimise physiological measurements that may add further objectivity to the effects of novel treatments on underlying pathophysiology.

Effective treatment for Raynaud's phenomenon remains an important unmet need. Clearly more work is needed in this area and it is pleasing that the Scleroderma Clinical Trials Consortium (SCTC) and other groups are working on this to try to develop better outcomes and avoid disappointing studies that may not reflect the true potential of candidate therapeutic interventions.

Yours sincerely

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