

Drug does not reduce digital ulcers in patients with systemic sclerosis

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In an article appearing in the May 10, 2016 issue of *JAMA*, Dinesh Khanna, M.D., of the University of Michigan Scleroderma Program, Ann Arbor, and colleagues evaluated the efficacy of the drug macitentan in reducing the number of new digital ulcers in patients with systemic sclerosis.

Systemic sclerosis is a chronic multisystem autoimmune disease and multiorgan disease affecting the [connective tissue](#) of the skin and several internal organs. Digital ulcers occur in 35 percent to 68 percent of [patients](#) with [systemic sclerosis](#) and are associated with pain, disfigurement, poor quality of life, and disability. For this study, two clinical trials (DUAL-1, DUAL-2) were conducted in which patients with systemic sclerosis and active digital (finger) ulcers at trial entry were randomly assigned to receive oral doses of 3 mg of macitentan, 10 mg of macitentan, or placebo once daily and stratified according to number of digital ulcers at baseline. Macitentan is a drug approved for long-term treatment of [pulmonary arterial hypertension](#).

In DUAL-1, among 289 randomized patients, 226 completed the study. Among 265 patients randomized in DUAL-2, 216 completed the study. The researchers found that macitentan did not reduce the cumulative number of new digital ulcers over 16 weeks compared with placebo. Regardless of treatment, patients had few new digital ulcers, and their overall digital ulcer condition remained stable over 16 weeks.

Adverse events more frequently associated with macitentan than with

placebo were headache, peripheral edema, skin ulcer, anemia, upper [respiratory tract infection](#) and diarrhea.

"These results do not support the use of macitentan for the treatment of digital ulcers in this patient population," the authors write.

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