

Case raises concern that sotatercept may be associated with serious and recurrent gastrointestinal bleeding

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Physicians should be aware of a potential serious adverse effect associated with sotatercept use. A case report detailing serious and

recurrent gastrointestinal bleeding is published in *Annals of Internal Medicine*.

Sotatercept is an investigational medicine that has shown positive results for treating adults with pulmonary arterial hypertension. In the phase 2 PULSAR and phase 3 STELLAR trials, epistaxis, skin telangiectasias, and thrombocytopenia were more frequent among those taking sotatercept compared with placebo. To date, sotatercept has not been associated with recurrent gastrointestinal bleeding.

Researchers from Beth Israel Deaconess Medical Center and Tufts Medical Center describe the case of a 68-year-old woman with [pulmonary arterial hypertension](#) who received sotatercept for approximately 12 months during the phase 3 clinical trial STELLAR and its long-term open-label extension (SOTERIA).

The patient was hospitalized for gastrointestinal bleeding on six instances while receiving sotatercept, which resolved when therapy was discontinued. It is not clear if sotatercept increases the risk for gastrointestinal bleeding. It is not clear if taking sotatercept increases risk for bleeding in the [digestive tract](#) or if it could cause unusual changes in the [blood vessels](#) in your stomach and intestines.

More research is needed to determine these issues or whether using sotatercept could lead to problems with [blood clotting](#), like having too few platelets, which might increase the risk of bleeding. This is an important point, especially for [older patients](#) who may have other blood vessel issues in the digestive system due to aging, such as angioectasias, or who may be on other blood-thinning agents.

More information: *Annals of Internal Medicine* (2023).
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