

FDA-approved clinical trial tests stem cells to heal wounds

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Sanford Health is launching its second adipose-derived stem cell clinical trial - this one to focus on non-healing leg wounds.

The trial, which opened in September with expanded criteria, is a phase 1 trial to study the safety and efficacy of using adipose-derived [stem cell therapy](#) as a treatment for non-healing leg ulcers.

It's open to participants ages 18 and older who have a wound 3-25 centimeters squared - or about 1 to 9 inches—and have an A1C less than nine. A non-healing leg ulcer is an open sore that has been present for at least three months.

"We have a mission here at Sanford - to use research and [clinical trials](#) to make a real difference in people's lives," said David Pearce, Ph.D., executive vice president of innovation and research at Sanford Health. "This clinical trial can help explore treatments for people with non-healing wounds, including people who have diabetes and others with conditions that affect their quality of life."

Sanford Health continues to focus on core missions, including research and diabetes. Sanford Research has been a pioneer in adipose stem cell research, most recently to study rotator cuff injuries. That trial was the first FDA-approved clinical trial using a person's own fat-derived [adult stem cells](#) to treat shoulder injuries.

"The researchers of Sanford Health are dedicated to safely testing how

adipose-device stem cells can heal the body," Pearce said. "We aim to truly legitimize the use of adult-derived [stem cells](#) for healing purposes in the United States."

More information: The trial will accept 36 participants. Bradley Coots, M.D., plastic surgeon at Sanford Health, is the trial's principal investigator. Clinical investigators in this study include vascular specialists from Sanford Wound Clinic in Sioux Falls. This team will conduct follow-up visits with participants after receiving the initial treatment. For information or to discuss qualifications, call 605-328-1368.

Provided by Sanford Health

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