

LEADER TIMES

Leg ulcer treatments tested at ACMH

By Tom Mitchell

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There may be new hope for the seven million or so Americans suffering with venous stasis, or vascular leg ulcers, thanks to an experimental program at ACMH Hospital. That hope comes from a land down under.

Dr. Thomas E. Serena said a six-week program is being offered to venous stasis ulcer patients who are willing to be part of a study using a combination of four-layer wraps and an experimental topical medication called Nexagon, developed by CoDa Therapeutics of Auckland, New Zealand. CoDa Therapeutics is a bio-pharmaceutical company specializing in wound care therapeutics. Serena said the program is free to anyone willing to participate in the study.

"We conduct an initial evaluation to determine eligibility," Serena said. "We will do blood studies and measure the size of the existing ulcer. If the patient is diabetic, we will consider their hemoglobin A1C. That is a test to determine their average glucose level over a three-month period. Our qualification guidelines are very liberal."

Serena said studies are being conducted at ACMH in East Franklin, Erie and Tulsa, Okla. Nearly 100 patients have been enrolled in the studies to date, but he said there is room for about 50 more. He added that so far the results look promising.

"We've suspected for some time that such wounds don't heal because the cells in the affected area communicate damage to one another telling surrounding cells to back off," he said. "Nexagon blocks that communication. Tests done in New Zealand and the U.K. revealed that the Nexagon molecule could acts as a 'blocker' molecule, much like members of a football team acting to clear a path for the quarterback."

Serena, principal investigator in the United States for CoDa Therapeutics, and Dr. Matthew Sabo, sub-investigator, said that recent tests indicate that Nexagon can not only reduce the size of ulcers but also reduce associated pain. Moreover, Nexagon has been used successfully in New Zealand and the U.K. to treat certain eye injuries to the cornea as well as other skin, brain or spinal cord injuries. Studies at ACMH are limited to venous stasis ulcers.

"Our studies are by no means complete," Serena said. "We have to analyze all the data we hope to collect and publish our findings by late summer. After that we will conduct a larger trial, called a Phase Three trial, to seek FDA (Food And Drug Administration) approval. That study will involve about 300 patients. Vascular ulcers, known as venous stasis ulcers, are quite common in the U.S. About seven million people suffer from them."

Serena stressed that the study is for patients with venous stasis ulcers but not for patients with diabetic foot ulcers. He said venous stasis ulcers usually appear on or near an ankle or some part of the leg, while diabetic foot ulcers usually appear on the bottom of the foot.

The studies are being conducted at the Elmer and Annabelle Snyder Institute for Vascular Health and Research at ACMH Hospital. Anyone interested in enrolling may contact Clinical Research Coordinator Heather Connell at 724-543-8536.

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