



▶ Purpose

The Phase 2b MATRIX trial will study the effects of Exellarate™ (GAM501) (Ad5PDGF-B/bovine Type I collagen gel) in men and women for the potential treatment of neuropathic non-healing diabetic foot ulcers. GAM501 is an investigational product designed to stimulate the process of wound healing.

▶ Study Title

MATRIX: A Phase 2b Study of GAM501 in the Treatment of Diabetic Ulcers in the Lower Extremities

▶ Study Design:

The MATRIX study is a randomized, double-blind, placebo-controlled, comparator arm (Standard of Care) safety and efficacy study to evaluate GAM501 (Ad5PDGF-B/bovine type I collagen gel) that is topically administered once or twice over the course of the study.

▶ Primary and Secondary Endpoints:

The primary endpoint will be the effect of GAM501 on the incidence of complete ulcer closure at 12 weeks or earlier. The secondary endpoints will include other measures of wound healing.

▶ Eligibility

- Patients 18 years of age and above with a lower extremity ulcer of the foot that is ≥ 1.5 and ≤ 10.0 cm² in size
- Patients must have a diagnosis of diabetes mellitus (Type I or II) requiring insulin or hypoglycemic agents to control blood sugars
- The patient's ulcer must have been present for ≥ 6 weeks prior to enrollment, must have adequate blood flow to the affected foot and be unable to perceive 10 grams of pressure
- Willing to adhere to wearing off-loading orthopedic shoe for up to 16 weeks

▶ Contact Information

For additional information about the MATRIX clinical study and enrollment information please contact <http://clinicaltrials.gov/ct/show/NCT00493051>, call Tissue Repair Company at 858-793-6641 or contact nearest site in your area from the clinical sites below.

Locations

United States, Arizona

- Aung Foothealth Clinics **Recruiting**
Tuscon, Arizona, United States, 85710
Contact: Chuck Heidenreich draung@theriver.com
Principal Investigator: Barbara Aung, DPM
- Banner Baywood Medical Center **Recruiting**
Mesa, Arizona, United States, 85206
Contact: Barbara Lambeth, RN Barbara.lambeth@bannerhealth.com
Principal Investigator: Mark Starling, MD
- Associated Foot & Ankle Specialists **Recruiting**
Phoenix, Arizona, United States, 85015
Contact: Norma Ramos sugie2468@netzero.net
Principal Investigator: Arthur Tallis, DPM

United States, California

- Northern California Foot/Ankle Center **Recruiting**
Santa Rosa, California, United States, 95403
Contact: Youlanda D'Costa noshib@aol.com
Principal Investigator: Walter D'Costa, DPM
- LAC-USC Medical Center **Not yet recruiting**
Los Angeles, California, United States, 90033
Contact: Javona Wright jwright@surgery.usc.edu
Principal Investigator: Warren Garner, MD
- Dr. Roy Kroeker DPM **Not yet recruiting**
Fresno, California, United States, 93710
Contact: Mary Kroeker mem-k@pacbell.net
Principal Investigator: Roy Kroeker, DPM
- Long Beach VA Health Care System **Recruiting**
Long Beach, California, United States, 90822
Contact: Kay Crosser 562-826-8190 kay.crosser@va.gov
Contact: Reza Azadegan 562-826-8000 ext 2887 reza.azadegan@va.gov
Principal Investigator: Ian Gordon, MD

United States, Connecticut

- North American Center for Limb Preservation **Recruiting**
New Haven, Connecticut, United States, 06515
Contact: Michael Palladino, DPM mpads1@aol.com
Principal Investigator: Peter Blume, DPM

United States, Florida

- Doctor's Research Network **Not yet recruiting**
Miami, Florida, United States, 33143
Contact: Yvette Salamanca jrhsbri@aol.com
Principal Investigator: Jason Hanft, DPM
- University of Miami **Recruiting**
Miami, Florida, United States, 33136
Contact: Carol Kittles ckittles@med.miami.edu
Principal Investigator: Robert Kirsner, MD PhD

Bay Pines VAHCS **Not yet Recruiting**
Bay Pines, Florida, United States, 33744
Contact: Diane Ochs, RN diane.ochs@med.va.gov
Principal Investigator: Wyatt Payne, MN

United States, Georgia
Village Podiatry Group **Recruiting**
Smyrna, Georgia, United States, 30080
Contact: David Helfman, DPM
Principal Investigator: Brent Nixon, DPM

United States, Illinois
Memorial Hospital **Recruiting**
Belleville, Illinois, United States, 62220
Contact: Marge Groom, RN hmoosa@charter.net
Principal Investigator: Hans Moosa, MD

United States, New York
New York Presbyterian Hospital **Recruiting**
New York, New York, United States, 10032
Contact: Michael Golinko 917-280-6363 mg2611@columbia.edu
Principal Investigator: Harold Brem, MD
Stony Brook University Medical Center **Recruiting**
Stony Brook, New York, United States, 11794
Contact: Eileen Finnin, RN efinnin@notes.cc.sunysb.edu
Principal Investigator: Antonio Gasparis, MD

United States, North Carolina
University of North Carolina **Recruiting**
Chapel Hill, North Carolina, United States, 27599
Contact: Nicole Lemire nlemire@med.unc.edu
Principal Investigator: William Marston, MD

United States, Pennsylvania
Warren General Hospital **Not yet recruiting**
Warren, Pennsylvania, United States, 16365
Contact: Chris Beuger cbeuger@healingwounds.com
Principal Investigator: Thomas Serena, MD

United States, Texas
University of Texas Medical Branch **Not yet recruiting**
Galveston, Texas, United States, 77555
Contact: Pamela Kiani 409-266-9441 pjkiani@utmb.edu
Principal Investigator: Maria Guidry, MD

