



▶ 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

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

Dr. Roy Kroeker DPM

Recruiting

Fresno, California, United States, 93710

Contact: Mary Kroeker mem-k@pacbell.net

Principal Investigator: Roy Kroeker, DPM

LAC-USC Medical Center

Recruiting

Los Angeles, California, United States, 90033

Contact: Javona Wright jwright@surgery.usc.edu

Principal Investigator: Warren Garner, MD

Foot Doctors of Watsonville

Not yet recruiting

Watsonville, California, United States, 95076

Contact: Juan Gutierrez 831-728-8844 juanlg82@sbcglobal.net

Principal Investigator: David Abdo, DPM

Absolute Foot Care

Not yet recruiting

Chula Vista, California, United States, 91910

Contact: Arlene Banares 619-370-9520 abanares4@yahoo.com

Principal Investigator: James Longobardi, DPM

Dr. Jagpreet Mukker

Not yet recruiting

Fresno, California, United States, 93726

Contact: Prabhi Mukker 559-224-5101 prabhimukker@gmail.com

Principal Investigator: Jagpreet Mukker, DPM

United States, Connecticut

North American Center for Limb Preservation

Recruiting

New Haven, Connecticut, United States, 06515

Contact: Michael Palladino, D.P.M. mpads1@aol.com

Principal Investigator: Peter Blume, DPM

United States, Florida

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

Recruiting

Bay Pines, Florida, United States, 33744

Contact: Diane Ochs, RN diane.ochs@med.va.gov

Principal Investigator: Wyatt Payne, MN

Karr Foot Kare

Not yet recruiting

Lakeland, Florida, United States, 33813

Contact: Teneca Brunner 863-646-5960 tbrunner1008@yahoo.com

Principal Investigator: Jeffrey Karr, DPM

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, Massachusetts

Boston Medical Center

Not yet recruiting

Boston, Massachusetts, United States, 02118
Contact: Jonathan LeBretton, RN, BSN 617-414-6833
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Principal Investigator: Vickie Driver, DPM

United States, Nevada

Advanced Foot & Ankle Center

Not yet recruiting

Las Vegas, Nevada, United States, 89119
Contact: Joseph Dove 702-696-9005 dovejm@yahoo.com
Principal Investigator: Cyaandi Dove, DPM

United States, New York

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

Division of Wound Healing & Regenerative Medicine NYU School of Medicine

Not yet recruiting

New York City, New York, United States, 10016
Contact: Michael Michael Golinko, MD 212-598-6000
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Principal Investigator: Harold Brem, MD

Mt. Sinai School of Medicine

Recruiting

New York City, New York, United States, 10029
Contact: Tanisha Brown 212-241-4028 tanisha.brown@mssm.edu
Principal Investigator: Peter Sheehan, 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

Recruiting

Warren, Pennsylvania, United States, 16365
Contact: Jack Marnoni jmarnoni@healingwounds.com
Principal Investigator: Thomas Serena, MD

United States, Texas

University of Texas Medical Branch

Recruiting

Galveston, Texas, United States, 77555

Contact: Pamela Kiani 409-266-9441 pjkiani@utmb.edu

Principal Investigator: Maria Guidry, MD

South Texas Foot Institute

Recruiting

San Antonio, Texas, United States, 78224

Contact: Diana Estrada 210-928-3668 dianaapollori@yahoo.com

Principal Investigator: Bhavesh Shah, DPM

Presbyterian Hospital of Dallas

Not yet recruiting

Dallas, Texas, United States, 75231

Contact: Mary Walraven 214-540-1821 mwalraven@wound.com

Principal Investigator: Jeff Stone

Sponsors and Collaborators

Tissue Repair Company Cardium Therapeutics

Investigators

Study Chair: Randall Moreadith, MD Ph.D

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