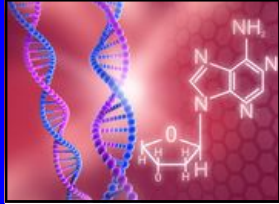




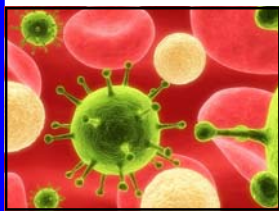
Hemangioma



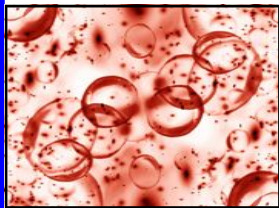
Gene Therapy



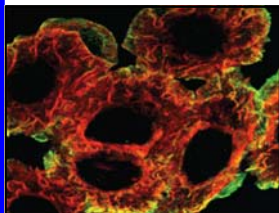
Bioengineered Skin



Antimicrobials



Angiogenesis



Growth Factors

# NewBridge

## MEDICAL RESEARCH

volume 6

Nov, 2009

### QUARTERLY UPDATE ON RESEARCH AND CLINICAL STUDIES

- CURRENT STUDIES

*8 major studies currently underway in six centers*

- UPCOMING CLINICAL TRIALS AND RESEARCH

*Major studies scheduled for 2010 including a national HBO trial*

- WELCOME TO:

COMMUNITY MEDICAL CENTER, SCRANTON PA

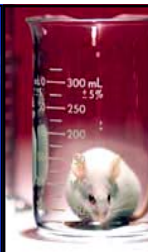
ST JOHNS HOSPITAL, TULSA, OK

- ABOUT US

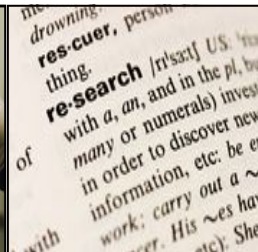
*NewBridge calls for volunteers*



Medical Devices



Animal Studies



EB



Hyperbaric Oxygen

# Current and Upcoming Clinical Trials

## December 2009

Clinical research is essential to advance our knowledge of wound healing. Following are trials currently being conducted and immediately anticipated. Additional trials will be added and/or completed over the coming months. This News Letter will be updated quarterly to keep you apprised of our progress.

### 1. A Prospective, Phase III, Multi-center, Randomized, Controlled Clinical Investigation of Dermagraft in Patients with Venous Leg Ulcers.

- Patients with venous leg ulcers receive standard of care (compression wraps) or standard of care plus up to eight applications of neonatal foreskin derived living human skin equivalent.
- All care is provided at no cost and a travel stipend is available.
- This trial is being conducted at:  
St. Vincent's Health Center. Erie, PA. Phone: 814- 452-7878.

### 2. A Randomized, Double-Blind, Vehicle-controlled, Parallel Group, Dose-Ranging, Multi-center Study of the Efficacy and Safety of Nexagon® in the Treatment of participants with Venous Leg Ulcers.

- Patients with venous leg ulcers receive the standard of care in addition to either a placebo gel or one of two doses of a new topical medicine (Nexagon).
- The trial lasts six weeks. All care is provided at no cost and a travel stipend is available.
- This trial is being conducted at the following clinics:
  1. St. Vincent's Health Center. Erie, PA. (814) 452-7878.
  2. Snyder Institute for Vascular Health and Research. Armstrong County Memorial Hospital, Kittanning, PA. (724) 543-8536.
  3. St. Johns Wound Care Center. Tulsa, OK. (918)712-3377.

### 3. Analysis of Connexin Distribution in Various Skin Wounds. NEXULC-006. Ongoing.

- Patients with any wound are candidates for a study to determine the levels of Connexin 43. It is believed that elevated levels of Connexins are one of the primary reasons that wounds do not heal.
- Patients receive \$50 for participating.
- The trial involves a biopsy (the size of a pencil eraser) of the wound and the normal skin of the forearm.
- This trial is being conducted at:
  1. St. Vincent's Health Center. Erie, PA. (814) 452-7878.
  2. Snyder Institute for Vascular Health and Research, Armstrong County Memorial Hospital Kittanning, PA. (724) 543-8536.
  3. Warren General Hospital. Warren, PA (814) 726-2594.
  4. Bradford Regional Medical Center. Bradford, PA. (814) 362-8230.
  5. Grove City Medical Center. Grove City, PA. (724 ) 450-7000

#### **4. The Healing Of Diabetic Ulcers Using A Herbal Extract Impregnated Dressing.**

- Diabetic patients with foot ulcerations can enroll in a trial testing a novel wound healing agent recently discovered in Israel. We have partnered with Izun pharmaceuticals as one of only four sites to test the product in the United States.
- The trial is for six weeks. All care is provided at no cost including a boot to relieve pressure on the foot.
- The trial is being conducted at:  
St. Vincent's Health Center. Erie, PA. (814) 452-7878.

#### **5. A Randomized Trial of the Flexitouch® System as an Adjunctive Treatment for Venous Stasis Ulcer.**

- Patients with venous leg ulcers also suffer from swelling of the lower extremities, called lymphedema. The Flexitouch system is designed to reduce swelling in the lower extremities.
- Patients will receive the treatment with the Flexitouch device at no cost.
- This trial is being conducted at:
  1. Snyder Institute for Vascular Health and Research, Armstrong County Memorial Hospital. Kittanning, PA. (724) 543-8536.
  2. Scranton Community Medical Center. Scranton, PA (570) 969-8000.

#### **6. A Study to Determine the diagnostic accuracy of the ExpressDetect® wound pathogen diagnostic test relative to the gold standard in diabetic foot ulcers, pressure ulcers, or chronic wounds caused by venous insufficiency.**

- This trial has been funded by the National Institutes of Health (NIH). We are studying a novel device for the detection of bacteria in wounds. This test will be compared to standard culture techniques.
- This trial is planned for numerous sites in the Serena Group system including:
  1. St. Vincent's Health Center. Erie, PA. (814) 452-7878.
  2. Snyder Institute for Vascular Health and Research, Armstrong County Memorial Hospital Kittanning, PA. (724) 543-8536.
  3. Warren General Hospital. Warren, PA (814) 726-2594.
  4. Bradford Regional Medical Center. Bradford, PA. (814) 363-9484.
  5. Grove City Medical Center. Grove City, A. (724) 450-7000.Other sites in our system are likely to be added.

#### **7. Evaluation of A Medical Food For Chronic Wounds**

- Patients with diabetic foot ulcers are candidates for this clinical trial.
- Patients receive the supplement (or placebo) at no cost.
- This trial is being conducted at:  
Snyder Institute for Vascular Health and Research, Armstrong County Memorial Hospital. Kittanning, PA. (724) 543-8536.

#### **8. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study of the Safety and Efficacy of Thymosin Beta 4 in the Treatment of Patients with Epidermolysis bullosa.**

- Patients suffering with Epidermolysis bullosa, a congenital skin disease resulting in open skin lesions, are candidates for a clinical trial evaluating a new medication applied topically.
- All of the care is provided at no cost to the patient/family. Travel stipends are available.
- This trial is being conducted at:  
St. Vincent's Health Center. Erie, PA. (814) 452-7878.

## Serena Group Welcomes New Research Centers:

Scranton Community Hospital, Scranton, PA

Dr. Edward Batzel MD FACS , Principal Investigator

Rose Mary Sciandra, RN, Coordinator

St Johns Hospital, Tulsa Ok

Dr Lam Le, MD, Principal Investigator

## Upcoming Trials scheduled for 2010

1. A Prospective, real World Multiple Treatment Multi-Center Clinical Study to Evaluate the Efficacy, Safety and Comparative Effectiveness of Hyperbaric Oxygen in combination with Best Practices in the Treatment of Wagner III Diabetic Foot Ulcers. Planned submission to ethics committee in late 2009.
2. NorLeu-Angiotensin Topical gel in the treatment of diabetic foot ulcers. Awaiting Ethics committee approval. Planned for the Warren General Hospital Wound Care Center. Warren, PA. (814) 723-2594.
3. Integra™ vs. Standard of Care in diabetic foot ulcerations. Planned start December 2009 pending regulatory and ethics committee approvals. Sites to be determined.

Multiple additional studies and clinical trials and research studies are in development.

## ABOUT US

NewBridge Medical Research has conducted more than 40 clinical trials, ranging from novel antibiotics to bioengineered skin, growth factors, and platelet gels.

NewBridge is recognized internationally as being in the forefront of wound healing research. Our large patient volume affords us the ability to conduct clinical trials for all of the major pharmaceutical and device companies.

We conduct research at all of our wound care clinics, which has resulted in more than 75 published papers and over 175 presentations worldwide. Our clinical trials make novel treatments available to a patient population with diabetes and venous insufficiency while providing a modest revenue stream for our hospitals.

For additional information regarding research and clinical trials, please contact us at [www.serenagroup.net](http://www.serenagroup.net) or (814) 688-4000

**SerenaGroup**  
building the nation's leading wound care team.

[www.serenagroup.net](http://www.serenagroup.net)