**Appendix E. Ongoing/Recently Completed Studies Related to Treatment of Chronic Venous Leg Ulcers**

| **Title/ Identifier(s)** | **Study Dates** | **Description** | **Sponsor or Principal Investigator**  **Collaborator(s)** | **Source** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **1. Title:**  Pivotal Trial of Dermagraft(R) to Treat Venous Leg Ulcers (DEVO)  **Identifier(s):**  NCT00909870 | **Start date:**  June 2009  **Estimated study completion date:**  August 2011  **Estimated primary completion date:**  May 2011 (Final data collection date for primary outcome measure) | **Purpose:**  This study randomly assigns patients with venous leg ulcers to receive standard therapy (compression) alone or compression plus Dermagraft(R). Dermagraft is a device containing live human fibroblasts grown on an absorbable Vicryl mesh.  **Study design:**  Allocation: Randomized  Endpoint Classification: Safety/Efficacy Study  Intervention Model: Parallel Assignment  Masking: Open Label  Primary Purpose: Treatment  **Condition(s):**  Venous Leg Ulcer  **Intervention(s):**  Device: Dermagraft(R)  Device: Profore  **Estimated enrollment:** 537 | **Sponsor or PI and Collaborator(s):**  Shire Regenerative Medicine, Inc. | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT00909870](http://clinicaltrials.gov/ct2/show/NCT00909870) | Evaluates Dermagraft + profore compressions vs just profore compression |
| **2. Title:**  Taliderm Dressing for Venous Ulcers  **Identifier(s):**  NCT00720239 | **Start date:**  February 2008  **Estimated study completion date:**  August 2010  **Estimated primary completion date:**  September 2009 (Final data collection date for primary outcome measure) | **Purpose:**  To determine whether the TalidermR Wound Dressing, a poly-N-acetyl glucosamine (pGlcNAc) derived membrane material expedites wound healing in humans with venous stasis ulcers.  **Study design:**  Allocation: Randomized  Endpoint Classification: Safety/Efficacy Study  Intervention Model: Single Group Assignment  Masking: Open Label  Primary Purpose: Treatment  **Condition(s):**  Venous Stasis Ulcers  Venous Insufficiency  **Intervention(s):**  Other: Taliderm wound healing dressing  **Estimated enrollment:** 50 | **Sponsor OR PI and Collaborator(s):**  Medical University of South Carolina | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT00720239](http://clinicaltrials.gov/ct2/show/NCT00720239) | Phase 0 study, very small groups, not powered |
| **3. Title:**  FGF-1 for Topical Administration for the Treatment of Diabetic or Venous Stasis Ulcers  **Identifier(s):**  NCT00425178 | **Start date:**  September 2005  **Estimated study completion date:**  Not given  **Estimated primary completion date:**  Not given | **Purpose:**  Pilot Study to Evaluate the Safety and Tolerability of Human Fibroblast Growth Factor-1 (FGF-1) in Patients With Diabetic or Venous Stasis Ulcers  **Study design:**  Allocation: Non-Randomized  Endpoint Classification: Safety/Efficacy Study  Intervention Model: Single Group Assignment  Masking: Open Label  Primary Purpose: Treatment  **Condition(s):**  Chronic Wounds  Diabetes  Venous Stasis Ulcers  **Intervention(s):**  Drug: FGF-1  **Estimated enrollment:** 8 | **Sponsor OR PI and Collaborator(s):**  CardioVascular BioTherapeutics, Inc. | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT00425178](http://clinicaltrials.gov/ct2/show/NCT00425178) | Early pilot study |
| **4. Title:**  A Study to Investigate the Efficacy, Safety and Tolerability of Nexagon® as a Topical Treatment for Subjects With Venous Leg Ulcers (NOVEL2)  **Identifier(s):**  NCT01199588 | **Start date:**  May 2011  **Estimated study completion date:**  March 2013  **Estimated primary completion date:**  December 2012 (Final data collection date for primary outcome measure) | **Purpose:**  To determine if NEXAGON plus compression bandaging is more effective that placebo plus compression bandaging.  **Study design:**  Allocation: Randomized  Endpoint Classification: Safety/Efficacy Study  Intervention Model: Parallel Assignment  Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)  Primary Purpose: Treatment  **Condition(s):**  Venous Leg Ulcers  **Intervention(s):**  Drug: Nexagon® Low Dose  Drug: Nexagon® High Dose  Drug: Nexagon® Vehicle  **Estimated enrollment:** 300 | **Sponsor OR PI and Collaborator(s):**  CoDa Therapeutics Inc. | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT01199588](http://clinicaltrials.gov/ct2/show/NCT01199588) |  |
| **5. Title:**  Improving wound healing in chronic ulcus cruris venosum with native fibrin enriched with endogenous thrombocytes (controlled prospective randomized study)  **Identifier(s):**  EudraCT Number: 2007-005612-91 | **Start date:**  2008-04-30  **Estimated study completion date:**  Ongoing  **Estimated primary completion date:**  Ongoing | **Purpose:**  To evaluate the postulated improvement in wound healing with additive application of autologous fibrin enriched with autologous thrombocytes in the treatment of chronic crural venous  **Study design:**  Controlled prospective randomized study  **Condition(s):**  Ulcerated varicose veins  **Intervention(s):**  autologous fibrin enriched with autologous thrombocytes  **Estimated enrollment:** 40 | **Sponsor OR PI and Collaborator(s):**  Sektion Chirurgische Forschung, Univ.Klinik f.Chirurgie | EU Clinical Trials Register  **Accessed at:**  [www.clinicaltrialsregister.eu/ctr-search/trial/2007-005612-91/AT](https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-005612-91/AT) | Small study comparing aullogous fibrin with standard care; ranodmized not blinded; underpowered |
| **6. Title:**  Evaluate the Impact of Drawtex in Venous Leg Ulcers  **Identifier(s):**  NCT01319123 | **Start date:**  October 2010  **Estimated study completion date:**  August 2011  **Estimated primary completion date:**  August 2011 (Final data collection date for primary outcome measure) | **Purpose:**  To comparatively evaluate the impact of Drawtex wound dressing against wound bioburden in moderately to highly exuding venous leg ulcers.  **Study design:**  Allocation: Non-Randomized  Endpoint Classification: Efficacy Study  Intervention Model: Single Group Assignment  Masking: Open Label  Primary Purpose: Treatment  **Condition(s):**  Moderatley to Highly Exuding Venous Leg Ulcers  **Intervention(s):**  Device: Drawtex dressing  **Estimated enrollment:** 10 | **Sponsor OR PI and Collaborator(s):**  Southwest Regional Wound Care Center  Beier Drawtex Healthcare, (PTY). Ltd | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT01319123](http://clinicaltrials.gov/ct2/show/NCT01319123) | Nonrandomized small dressing study |
| **7. Title:**  Wound Fluid Protease Levels During Use of Novel Wound Dressing  **Identifier(s):**  NCT01567150 | **Start date:**  February 2012  **Estimated study completion date:**  February 2013  **Estimated primary completion date:**  December 2012 (Final data collection date for primary outcome measure) | **Purpose:**  To characterize the way leg wounds respond to a new type of wound dressing, compared with wounds in patients who are not using the new dressing.  **Study design:**  Allocation: Randomized  Intervention Model: Parallel Assignment  Masking: Open Label  Primary Purpose: Treatment  **Condition(s):**  Venous Stasis Ulcers  **Intervention(s):**  Device: Novel Dressing  **Estimated enrollment:** 40 | **Sponsor OR PI and Collaborator(s):**  Hollister Incorporated | ClinicalTrials.gov  **Accessed at:**  [clinicaltrials.gov/ct2/show/NCT01567150](http://clinicaltrials.gov/ct2/show/NCT01567150) | Biochemical analysis study—not specifically focused on healing |
| **8. Title:**  A study to research if foam sclerotherapy of saphenous trunks can speed up the healing of chronic venous leg ulcers  **Identifier(s):**  EudraCT Number: 2005-001551-38 | **Start date:**  2005-09-29  **Estimated study completion date:**  Ongoing  **Estimated primary completion date:**  Ongoing | **Purpose:**  To determine the effect of foam sclerotherapy on the incompetent venous trunks and the effect of foam sclerotherapy in addition to compression therapy on ulcer healing  **Study design:**  Randomized controlled trial  **Condition(s):**  patients with insufficiency of the long and/or short saphenous vein as underlying cause of their venous leg ulcer  **Intervention(s):**  foam sclerotherapy of saphenous trunks  **Estimated enrollment:** 200 | **Sponsor OR PI and Collaborator(s):**  Gloucestershire Hospitals NHS Foundation Trust | EU Clinical Trials Register  **Accessed at:**  [www.clinicaltrialsregister.eu/ctr-search/trial/2005-001551-38/GB](https://www.clinicaltrialsregister.eu/ctr-search/trial/2005-001551-38/GB) |  |
| **9. Title:**  A Phase II, Randomized, Prospective, Double blind, Parallel group, Multi-center Study to determine the Safety and Efficacy of GRANEXIN GEL in the Treatment of Venous Leg Ulcers  **Identifier(s):**  CTRI/2011/09/001985 | **Start date:**  11-10-2011  **Estimated study completion date:**  Not stated  **Estimated primary completion date:**  Not stated | **Purpose:**  To study the Safety and Efficacy of GRANEXIN GEL plus Standard of Care in comparison to Standard of Care alone in the Treatment of Venous Leg Ulcer  **Study design:**  Randomized, Prospective, Double blind, Parallel group, Multi-center Study  **Condition(s):**  Venous Leg Ulcers  **Intervention(s):**  GRANEXIN GEL plus Standard of Care  **Estimated enrollment:** 92 | **Sponsor OR PI and Collaborator(s):**  FirstString Research Inc | The World Health Organization Clinical Trials Registry  **Accessed at:**  [apps.who.int/trialsearch/Trial.aspx?TrialID=CTRI/2011/09/001985](http://apps.who.int/trialsearch/Trial.aspx?TrialID=CTRI/2011/09/001985) |  |