**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: RandomizedEndpoint Classification: Safety/Efficacy StudyIntervention Model: Parallel AssignmentMasking: Open LabelPrimary 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: RandomizedEndpoint Classification: Safety/Efficacy StudyIntervention Model: Single Group AssignmentMasking: Open LabelPrimary Purpose: Treatment**Condition(s):** Venous Stasis UlcersVenous 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-RandomizedEndpoint Classification: Safety/Efficacy StudyIntervention Model: Single Group AssignmentMasking: Open LabelPrimary Purpose: Treatment**Condition(s):** Chronic WoundsDiabetesVenous 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: RandomizedEndpoint Classification: Safety/Efficacy StudyIntervention Model: Parallel AssignmentMasking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)Primary Purpose: Treatment**Condition(s):** Venous Leg Ulcers**Intervention(s):** Drug: Nexagon® Low DoseDrug: Nexagon® High DoseDrug: 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-RandomizedEndpoint Classification: Efficacy StudyIntervention Model: Single Group AssignmentMasking: Open LabelPrimary 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 CenterBeier 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: RandomizedIntervention Model: Parallel AssignmentMasking: Open LabelPrimary 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) |  |