Trial record **1 of 1** for: NCT00909870

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Pivotal Trial of Dermagraft(R) to Treat Venous Leg Ulcers (DEVO)

ClinicalTrials.gov Identifier: NCT00909870

Recruitment Status : Completed
First Posted : May 29, 2009
Results First Posted : February 4, 2013
Last Update Posted : June 18, 2018

Sponsor:

Organogenesis

Information provided by (Responsible Party):

Organogenesis

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Venous Leg Ulcer
Interventions	Device: Dermagraft(R) Device: Profore
Enrollment	537

Participant Flow

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Recruitment Details	Screening commenced in May 2009 and ended in November 2010. Study sites included vascular surgery, dermatology, and podiatry clinics. A total of 913 potential subjects were screened across 58 study centers; 395 subjects were screen failures. A total of 537 subjects were enrolled across 49 study centers.
Pre-assignment Details	Prior to study enrollment, all subjects signing informed consent proceeded through a two-week run-in phase in which all subjects received standard-of-care study ulcer treatment. During this phase, any subject not meeting inclusion/exclusion criteria was considered a screen failure and removed from the study.

Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of-Care)	Active Control (Standard-of-Care)
▼ Arm/Group Description	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement.	Weekly application of compression dressings only, in combination with systematic surgical wound debridement.
Period Title: **Overall Study**		
Started	274	263
Completed	251	236
Not Completed	23	27
Reason Not Completed		
Adverse Event	13	7
Protocol Violation	1	2
Withdrawal by Subject	5	8
Lost to Follow-up	3	3
Physician Decision	0	2
Other	1	5

Baseline Characteristics

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Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of-Care)	Control (Standard-of-Care)	Total
▼ Arm/Group Description	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement	Weekly application of compression dressings only, in combination with systematic surgical wound debridement	Total of all reporting groups

		surgical wound debridement.	debridement.	
Overall Number of Baseline Participants		274	263	537
▼ Baseline Analysis Population Description		[Not Specified]		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years				
	Number Analyzed	274 participants	263 participants	537 participants
		63.1 (13.04)	63.2 (14.46)	63.1 (13.74)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	274 participants	263 participants	537 participants
	Female	158 57.7%	146 55.5%	304 56.6%
	Male	116 42.3%	117 44.5%	233 43.4%
Region of Enrollment Measure Type: Number Unit of measure: Participants	Number Analyzed	274 participants	263 participants	537 participants

United States		94	93	187
Estonia		10	9	19
Poland		81	74	155
South Africa		73	71	144
Germany		8	8	16
United Kingdom		6	7	13
Sweden		2	1	3
Ulcer Size Median (Full Range) Unit of measure: Centimeters-squared				
	Number Analyzed	274 participants	263 participants	537 participants
		5.75 (1.5 to 19.3)	5.90 (2.0 to 24.8)	5.9 (1.5 to 24.8)
Ulcer Duration Median (Full Range) Unit of measure: Days				
	Number Analyzed	274 participants	263 participants	537 participants
		206 (1 to 18157)	228 (23 to 3834)	214 (1 to 18157)

Outcome Measures

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1. Primary Outcome

Title	Complete Healing of the Study Ulcer by Week 16.
▼ Description	[Not Specified]
Time Frame	16 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Intent-to-Treat population

Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of-Care)	Control (Standard-of-Care)
▼ Arm/Group Description:	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement.	Weekly application of compression dressings only, in combination with systematic surgical wound debridement.
Overall Number of Participants Analyzed	274	263
Measure Type: Number Unit of Measure: participants		
	201	176

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Investigational Treatment (Dermagraft Plus Standard-of-Care), Control (Standard-of-Care)
	Comments	H0: the proportion of responders in the Dermagraft group = the proportion of responders in the Control group. HA: the proportion of responders in the Dermagraft group ≠ the proportion of

		responders in the Control group. The proportion of responders in the Dermagraft group was compared with the proportion of responders in the control group using the uncorrected chi-square test for 2x2 contingency tables. The difference between the groups was expected to be 13%.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.1030
	Comments	This p-value did not meet the prespecified threshold for statistical significance of < 0.05
	Method	Chi-squared
	Comments	Unadjusted
Method of Estimation	Estimation Parameter	Difference in proportions
	Estimated Value	6.5
	Estimation Comments	[Not Specified]

2. Secondary Outcome

Title	Time-to-Complete Healing
▼ Description	Kaplan-Meier survival analysis of the time to achieve median (50%) Complete Healing response in each treatment group.
Time Frame	From Week 0 visit to date subject's completely healed ulcer is 1st recorded as healed. If subject's ulcer not healed at 16 weeks, the "time until CH" was censored at 112 days.

▼ Outcome Measure Data

▼ Analysis Population Description
Intent-to-Treat population

Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of=-Care)	Control (Standard-of-Care)
▼ Arm/Group Description:	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement.	Weekly application of compression dressings only, in combination with systematic surgical wound debridement.
Overall Number of Participants Analyzed	274	263
Median (Inter-Quartile Range) Unit of Measure: days		
	58 (36 to 113)	64 (36 to 113)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Investigational Treatment (Dermagraft Plus Standard-of=- Care), Control (Standard-of-Care)
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.4046
	Comments	This p-value did not meet the prespecified threshold for statistical significance of < 0.05
	Method	Log Rank
	Comments	[Not Specified]
Method of	Estimation Parameter	Median Difference (Final Values)

Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	6
	Estimation Comments	[Not Specified]

3. Other Pre-specified Outcome

Title	Complete Healing by Week 16: Ulcers <= 12 Months Duration
▼ Description	[Not Specified]
Time Frame	16 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Pre-specified Subgroup of the Intent-to-Treat Population

Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of-Care)	Control (Standard-of-Care)
▼ Arm/Group Description:	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement.	Weekly application of compression dressings only, in combination with systematic surgical wound debridement.
Overall Number of Participants Analyzed	198	189
Measure Type: Number Unit of Measure: participants		
	158	132

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Investigational Treatment (Dermagraft Plus Standard-of-Care), Control (Standard-of-Care)
	Comments	Pre-specified subgroup analysis of the primary endpoint
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0239
	Comments	Unadjusted
	Method	Chi-squared
	Comments	Unadjusted
Method of Estimation	Estimation Parameter	Difference in proportions
	Estimated Value	10.0
	Estimation Comments	[Not Specified]

Adverse Events

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Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Investigational Treatment (Dermagraft Plus Standard-of-Care)	Control (Standard-of-Care)
Arm/Group Description	Weekly applications of Dermagraft and compression dressings, in combination with systematic surgical wound debridement.	Weekly application of compression dressings only, in combination with systematic surgical wound debridement.

All-Cause Mortality

	Investigational Treatment (Dermagraft Plus	**Control (Standard-of-Care)**

	Investigational Treatment (Dermagraft Plus Standard-of-Care)		Control (Standard-of-Care)	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

Serious Adverse Events

	Investigational Treatment (Dermagraft Plus Standard-of-Care)		Control (Standard-of-Care)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	28/274 (10.22%)		24/263 (9.13%)	
Blood and lymphatic system disorders				
Anemia	1/274 (0.36%)	1	0/263 (0.00%)	0
Cardiac disorders				
Acute Myocardial Infarction	0/274 (0.00%)	0	1/263 (0.38%)	1
Angina Unstable	0/274 (0.00%)	0	1/263 (0.38%)	1
Atrial Fibrilation	0/274 (0.00%)	0	3/263 (1.14%)	3
Cardiac Failure	0/274 (0.00%)	0	1/263 (0.38%)	1
Cardiac failure congestive	0/274 (0.00%)	0	2/263 (0.76%)	2
Cardio-respiratory arrest	0/274 (0.00%)	0	1/263 (0.38%)	1
Coronary artery disease	1/274 (0.36%)	1	0/263 (0.00%)	0
Myocardial infarction	1/274 (0.36%)	1	0/263 (0.00%)	0
Sick Sinus Syndrome	0/274 (0.00%)	0	1/263 (0.38%)	1
Gastrointestinal disorders				
Constipation	1/274 (0.36%)	1	0/263 (0.00%)	0
Diarrhea	0/274 (0.00%)	0	1/263 (0.38%)	1
Gastrointestinal haemorrhage	0/274 (0.00%)	0	1/263 (0.38%)	1
Inguinal hernia	0/274 (0.00%)	0	1/263 (0.38%)	1

General disorders				
Asthenia	1/274 (0.36%)	1	1/263 (0.38%)	1
Death	3/274 (1.09%)	3	2/263 (0.76%)	2
Drug intolerance	1/274 (0.36%)	1	0/263 (0.00%)	0
Oedema peripheral	0/274 (0.00%)	0	1/263 (0.38%)	1
Infections and infestations				
Abscess	1/274 (0.36%)	1	0/263 (0.00%)	0
Abscess limb	1/274 (0.36%)	1	0/263 (0.00%)	0
Appendicitis	0/274 (0.00%)	0	1/263 (0.38%)	1
Bronchitis	0/274 (0.00%)	0	2/263 (0.76%)	2
Cellulitis	2/274 (0.73%)	2	1/263 (0.38%)	1
Clostridial infection	1/274 (0.36%)	1	0/263 (0.00%)	0
Gastroenteritis	0/274 (0.00%)	0	1/263 (0.38%)	1
Infected skin ulcer	2/274 (0.73%)	2	2/263 (0.76%)	2
Laryngitis	0/274 (0.00%)	0	1/263 (0.38%)	1
Lower respiratory tract infection	1/274 (0.36%)	1	0/263 (0.00%)	0
Pelvic abscess	0/274 (0.00%)	0	1/263 (0.38%)	1
Peritonitis bacterial	1/274 (0.36%)	1	0/263 (0.00%)	0
Pneumonia	2/274 (0.73%)	2	3/263 (1.14%)	3
Sepsis	1/274 (0.36%)	1	1/263 (0.38%)	1
Upper respiratory tract infection	0/274 (0.00%)	0	1/263 (0.38%)	1
Urinary tract infection	1/274 (0.36%)	1	0/263 (0.00%)	0
Injury, poisoning and procedural complications				
Facial bones fractures	0/274 (0.00%)	0	1/263 (0.38%)	1
Hip fracture	1/274 (0.36%)	1	0/263 (0.00%)	0
Pelvic fracture	0/274 (0.00%)	0	1/263 (0.38%)	1

Pelvic fracture	0/274 (0.00%)	0	1/263 (0.38%)	1
Post procedural haematoma	1/274 (0.36%)	1	0/263 (0.00%)	0
Investigations				
Angiogram	0/274 (0.00%)	0	1/263 (0.38%)	1
Cardiac stress test	0/274 (0.00%)	0	1/263 (0.38%)	1
Metabolism and nutrition disorders				
Hypoglycemia	1/274 (0.36%)	1	1/263 (0.38%)	1
Musculoskeletal and connective tissue disorders				
Back pain	1/274 (0.36%)	1	0/263 (0.00%)	0
Joint effusion	0/274 (0.00%)	0	1/263 (0.38%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung neoplasm	0/274 (0.00%)	0	1/263 (0.38%)	1
Lung neoplasm malignant	0/274 (0.00%)	0	1/263 (0.38%)	1
Nervous system disorders				
Cerebrovascular accident	1/274 (0.36%)	1	0/263 (0.00%)	0
Epilepsy	0/274 (0.00%)	0	1/263 (0.38%)	1
Subarachnoid haemorrhage	0/274 (0.00%)	0	1/263 (0.38%)	1
Renal and urinary disorders				
Haematuria	1/274 (0.36%)	1	0/263 (0.00%)	0
Renal failure acute	1/274 (0.36%)	1	0/263 (0.00%)	0
Reproductive system and breast disorders				
Vaginal haemorrhage	1/274 (0.36%)	1	0/263 (0.00%)	0
Respiratory, thoracic and mediastinal disorders				
Acute respiratory distress syndrome	1/274 (0.36%)	1	0/263 (0.00%)	0

Chronic obstructive pulmonary disease	0/274 (0.00%)	0	1/263 (0.38%)	1
Cough	0/274 (0.00%)	0	1/263 (0.38%)	1
Dyspnoea	0/274 (0.00%)	0	1/263 (0.38%)	1
Interstitial lung disease	0/274 (0.00%)	0	1/263 (0.38%)	1
Pulmonary embolism	1/274 (0.36%)	1	0/263 (0.00%)	0
Pulmonary oedema	1/274 (0.36%)	1	0/263 (0.00%)	0
Skin and subcutaneous tissue disorders				
Erythema	0/274 (0.00%)	0	1/263 (0.38%)	1
Pupura	0/274 (0.00%)	0	1/263 (0.38%)	1
Surgical and medical procedures				
Implantable defibrilator replacement	1/274 (0.36%)	1	0/263 (0.00%)	0
Inguinal hernia repair	0/274 (0.00%)	0	1/263 (0.38%)	1
Therapy regimen changed	2/274 (0.73%)	2	0/263 (0.00%)	0
Varicose vein operation	0/274 (0.00%)	0	1/263 (0.38%)	1
Venous operation	1/274 (0.36%)	1	0/263 (0.00%)	0
Vascular disorders				
Hypertension	1/274 (0.36%)	1	0/263 (0.00%)	0
Hypertensive crisis	0/274 (0.00%)	0	1/263 (0.38%)	1

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Investigational Treatment (Dermagraft Plus Standard-of-Care)		Control (Standard-of-Care)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	168/274 (61.31%)		157/263 (59.70%)	

Total	166/274 (61.31%)		157/263 (59.70%)	
Infections and infestations				
Infected skin ulcer	22/274 (8.03%)	22	25/263 (9.51%)	25
Nasopharyngitis	18/274 (6.57%)	18	18/263 (6.84%)	18
Injury, poisoning and procedural complications				
Excoriation	20/274 (7.30%)	20	16/263 (6.08%)	16
Musculoskeletal and connective tissue disorders				
Pain in extremity	17/274 (6.20%)	17	25/263 (9.51%)	25
Skin and subcutaneous tissue disorders				
Skin Ulcer	77/274 (28.10%)	77	60/263 (22.81%)	60
Vascular disorders				
Hypertension	14/274 (5.11%)	14	13/263 (4.94%)	13

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Company-specific confidentiality agreement

Results Point of Contact

Name/Title:	Mollie Carter, MD, Medical Director
Organization:	Shire Regenerative Medicine
Phone:	(858) 754-5678
EMail:	mcarter@shire.com

Responsible Party:	Organogenesis
ClinicalTrials.gov Identifier:	NCT00909870 History of Changes
Other Study ID Numbers:	ABH-Dermagraft-001-08
First Submitted:	May 28, 2009
First Posted:	May 29, 2009
Results First Submitted:	December 31, 2012
Results First Posted:	February 4, 2013
Last Update Posted:	June 18, 2018