ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: November 14, 2016

ClinicalTrials.gov ID: NCT01770509

Study Identification

Unique Protocol ID: SHEBA -11- 9204-SG-CTIL

Brief Title: The Effect of the Cosmetic Cream NMBM on Leg Ulcers - a Pilot Study

Official Title: A Randomized, Parallel Group, Controlled Study to Assess the Efficacy and Safety of NMBM in the Treatment of Subjects With a Post-cellulitis and Venous Leg Ulcer

Secondary IDs:

Study Status

Record Verification: June 2016

Overall Status: Completed

Study Start: February 2013

Primary Completion: February 2015 [Actual] Study Completion: February 2015 [Actual]

Sponsor/Collaborators

Sponsor: M.D. Lederman Consulting Ltd

Responsible Party: Sponsor Collaborators:

Oversight

FDA Regulated?: No IND/IDE Protocol?: No

Review Board: Approval Status: Approved
Approval Number: 9204-11-SMC
Board Name: Sheba Medical Center IRB commitee
Board Affiliation: Sheba Medical Center
Phone: 972-3-530-3810
Email: :gita.veiber@sheba.health.gov.il Data Monitoring?: No

Plan to Share IPD?: Undecided

Oversight Authorities: Israel: Ethics Commission

Study Description

Brief Summary: Ulcers of the lower extremities, caused by chronic venous insufficiency and cellulitis are common in patients older than 65 years and cause a significant morbidity.

Natural Matrix Bio polymer Membrane (NMBM) is a novel topical cosmetic cream containing a mix of natural waxes, sugars and lipids. The aim of this study is to test whether of Natural Matrix Bio polymer Membrane (NMBM) is effective as an adjunctive therapy to the treatment of venous stasis and post-erysipelas leg ulcers.

Detailed Description: Ulcers of the lower extremities, particularly in patients older than 65 years, are common among the population. Studies estimate the prevalence of current chronic leg ulcers at approximately 1%. The most common cause (approximately 80%) is thought to be chronic venous insufficiency disease. Recurrent cellulitis is an additional common cause. The ulcers cause a significant morbidity and negative impact on the patients' quality of life. The care of chronic vascular ulcers places a significant burden on the patient and the health care system. Additionally, these nonhealing ulcers place the patient at much higher risk for lower extremity amputation.

Natural Matrix Bio polymer Membrane (NMBM) is a novel topical cosmetic cream containing a mix of natural waxes, sugars and lipids. The aim of this study is to test whether of Natural Matrix Bio polymer Membrane (NMBM) is effective as an adjunctive therapy to the treatment of venous stasis and post-erysipelas leg ulcers.

Conditions

Conditions: Ulcer
Venous Ulcer
Skin Ulcer
Leg Ulcer

Keywords: Chronic venous leg ulcers
Venous ulcer
Stasis ulcer
Varicose ulcer

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1/Phase 2

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Open Label

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 30 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Standard of care Standard of care: Dressings +Compression garments	Compression garments Compression garments Other Names: • Compression garments
Experimental: Application of NMBM Daily application of NMBM	Device: NMBM Daily application of NMBM in addition to compression therapy Compression garments Compression garments Other Names: • Compression garments

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 90 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

1. Signed and dated written Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approved informed consent obtained from the subject in accordance with the local regulations;
2. Male or female subjects, ≥18 to ≤90 years of age
3. Patient with venous or predominantly venous leg ulcer (ankle-brachial index > 0.8)
4. Chronic venous insufficiency or post-erysipelas ulcer
5. Ulcer size between 5 and 170 sq cm, inclusive
6. Ulcer present for at least one month
7. ankle-brachial index >0.7 Exclusion Criteria:

1. Suffers from diabetes mellitus with HbA1c ≥ 8%
2. Albumin less than

2. 2. Patients with the following abnormal laboratory test levels hemoglobin <10.5 g/dL platelet count <100 x 109/L serum albumin level < 2.5 g/dL 3. Suffers from clinically significant arterial disease 34. Has a known allergy to any of the compounds that are part of this protocol 45. Has evidence of the ulcer and / or infection extending to the underlying muscle, tendon or bone 56. Has used any investigational drug(s) within 30 days preceding randomization 67. Is unable to manage self-treatment 78. Is pregnant, nursing mother or a woman of child bearing potential who is not using an adequate form of contraception (or abstinence) 8. 9. Suffers from a condition which in the opinion of the Investigator would compromise the safety of the subject and / or the quality of the data 9. 10. Unwilling or unable to comply with study requirements.

Contacts/Locations

Study Officials: Shoshana Greenberger, MD PhD
Study Principal Investigator
The Department of Dermatology, Sheba Medical Center

Locations: Israel
The Department of Dermatology, Sheba Medical Center
Ramat-Gan, Israel, 52621

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Overall Study

	Standard of Care	Application of NMBM
Started	12	17
Completed	11	14
Not Completed	1	3
Injury	0	1
Lost to Follow-up	1	2

Baseline Characteristics

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Baseline Measures

		Standard of Care	Application of NMBM	Total
Overall Number of Participants		12	17	29
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	12 participants	17 participants	29 participants
		75.54 (7.7)	68.17 (13.9)	70.9 (12.6)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	12 participants	17 participants	29 participants
	Female	5 41.67%	9 52.94%	14 48.28%
	Male	7 58.33%	8 47.06%	15 51.72%
Region of Enrollment Measure Number Type: Unit of measure: participants	Number Analyzed	12 participants	17 participants	29 participants
Israel		12	17	29

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Logarithm of Percentage of Baseline Ulcer Size
Measure Description	Logarithm of percentage of baseline ulcer size. Log (ulcer area at 4 weeks/ulcer area at baseline *100) Ulcer area measured as longest ulcer length x longest ulcer width
Time Frame	From start of treatment to 4 weeks
Safety Issue?	No

Analysis Population Description

Analysis is based on measures from each ulcer, when some participants had more than one ulcer

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Measured Values

	Standard of Care	Application of NMBM
Number of Participants Analyzed	11	14
Number of Units Analyzed Type of Units Analyzed: Ulcers	17	19
Logarithm of Percentage of Baseline Ulcer Size Mean (Standard Deviation) Unit of measure: Mean of log (percentage of baseline area	3.6043 (2.16636)	3.5030 (2.11130)

Statistical Analysis 1 for Logarithm of Percentage of Baseline Ulcer Size

Statistical Analysis Overview	Comparison Groups	Standard of Care, Application of NMBM
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.652
	Comments	[Not specified]
	Method	ANOVA
	Comments	General Linear Model ANOVA with repeated measures

2. Secondary Outcome Measure:

Measure Title	Alleviation of Pain
Measure Description	Pain in week 4, assessed by the patient on a visual analogue pain score from 0 to 10. 0 represents no pain, 10 represents worst pain
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Measured Values

	Standard of Care	Application of NMBM
Number of Participants Analyzed	11	14
Alleviation of Pain Mean (Standard Deviation) Unit of measure: units on a scale	2.45 (1.29)	1.68 (1.62)

Statistical Analysis 1 for Alleviation of Pain

Statistical Analysis Overview	Comparison Groups	Standard of Care, Application of NMBM
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.645
	Comments	[Not specified]
	Method	ANOVA
	Comments	General Linear Model ANOVA with repeated measures

3. Secondary Outcome Measure:

Measure Title	Incidence of Adverse Events at 4 Weeks
Measure Description	Number of patients with adverse effects at 4 weeks
Time Frame	4 weeks
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Measured Values

	Standard of Care	Application of NMBM
Number of Participants Analyzed	11	14

Incidence of Adverse Events at 4 Weeks Measure Type: Number Unit of measure: Number of patients with adverse events	1	3

4. Secondary Outcome Measure:

Measure Title	Incidence of Adverse Events
Measure Description	Number of adverse effects at 4 weeks
Time Frame	4 weeks
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Measured Values

	Standard of Care	Application of NMBM
Number of Participants Analyzed	11	14
Incidence of Adverse Events Measure Type: Number Unit of measure: number of adverse effects	1	3

5. Secondary Outcome Measure:

Measure Title	Time to Complete Closure
Measure Description	
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description

Data was not collected as time to ulcer closure has been beyond the study period in the majority of patients

Reporting Groups

	Description
Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
	Description
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Measured Values

	Standard of Care	Application of NMBM
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description

Standard of Care	Standard of care: Dressings +Compression garments Compression garments: Compression garments
Application of NMBM	Daily application of NMBM NMBM: Daily application of NMBM in addition to compression therapy Compression garments: Compression garments

Serious Adverse Events

	Standard of Care	Application of NMBM
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/11 (0%)	0/14 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Standard of Care	Application of NMBM
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/11 (9.09%)	3/14 (21.43%)
Skin and subcutaneous tissue disorders		
local irritation [1] †	0/11 (0%)	3/14 (21.43%)
wound infection [2] †	1/11 (9.09%)	0/14 (0%)

† Indicates events were collected by systematic assessment.

[1] Local erythema or burning

[2] Secondary infection of wound treated by antibiotics

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.