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eProst #: 20210621
Principal Investigator: Hadar Lev-Tov, MD
Study Title: A bioelectric dressing for Post De-Roofing Treatment of Hidradenitis Suppurativa

NCT #: NCT05057429

1) Objectives:

Our overall hypothesis is that a bioelectric dressing will enhance wound healing rate in people with hidradenitis suppurativa (HS) undergoing a deroofing procedure. We further hypothesize that in this population a bioelectric dressing will improve the following short- and medium-term outcomes: pain, range of motion and recurrence rate. We also hypothesize that this effect will be at least partially mediated by reduced inflammation. Finally, we hypothesize that the microbiome of treated wounds will be different compared to controls.

Our specific hypotheses for this project are:

- H1: The healing rate of post-surgical wounds, as determined by area reduction over time will be higher in the treatment group.
- H2: The time to complete healing will be shorter in the treatment group.
- H3: The short-term recurrence rate, as defined by new nodules or tunnels in the treated area at the week 8 visit, will be lower in the treatment group.
- H4: The microbiome population as characterized by whole shotgun metagenomic sequencing will significantly differ between the treatment groups at days 14 and 28 compared to day 0.

2) Background:

Hidradenitis Suppurativa (HS) is a chronic inflammatory disease characterized by painful inflammatory skin nodules, abscesses and tunneling wounds. Global estimates of prevalence for HS vary between 0.03% and 4%.[1] Currently, part of standard of care for HS tunnels is a de-roofing procedure in which the skin above the tunnel is excised and the tunnel is then allowed to heal by secondary intention. This tissue-saving surgical technique is generally reserved for patients with mild-to-moderate HS. However, there exist unmet needs as the de-roofing procedure is accompanied by pain and prolonged healing time. Additionally, it remains unclear whether de-roofing prevents localized recurrence of disease. Treatment after de-roofing remains a clinical challenge due to the location of wounds in skin folds of young, active patients. Still further, dressings used post-surgical intervention are only inclusive of moistened plain gauze; specialized dressings, however, may help facilitate healing time and improve patient outcomes. Procellera®, a specialized bioelectric wound dressing that generates electricity to support the body's natural healing process, may be a potential therapy for patients with HS who have undergone deroofing procedures.

Procellera®, a specialized wound dressing with microcurrent technology, has demonstrated electricidal antimicrobial efficacy[2,3] and enhances wound repair.[4-7] Procellera® has been shown to enhance wound repair through faster keratinocyte migration[4], increased re-

epithelialization rate[5,6], and reduced healing time[5-7]. Additionally, galvanic coupled elemental zinc and copper microparticles which make up Procellera®, have anti-inflammatory effects on skin mediated via anti TNF-Alpha and interlukin-1[8]. These pathways have been implicated in the pathogenesis of HS[9].

Here, we propose a pilot study to determine if Procellera® accelerates healing and reduces signs of inflammation, including pain, after de-roofing of HS tunnels. 12 patients with at least two axillary HS tunnels will be recruited to participate in the study to undergo a same day dual de-roofing procedure with Procellera® applied onto one of the post-procedure sites. The patients will be followed 3 days after surgery, 1 week after surgery, 2 weeks after surgery, 4 weeks after surgery and 8 weeks after surgery. If acceptable, a future study will be conducted with longer term, follow up of participants.

3) Inclusion and Exclusion Criteria*

Inclusion criteria

1. Adults 18 years old and older.
2. Have diagnosis of HS confirmed by a dermatologist.
3. Have at least two axillary tunnels in separate anatomical sites.
4. Able to provide informed consent.

Exclusion criteria:

1. Individuals who are not yet adults.
2. Subject is allergic to any of the materials and dressings involved in the procedures.
3. Women known to be pregnant.
4. Prisoners.
5. Subjects, who in the opinion of the PI, cannot comply with hope application of the treatment.

4) Number of Subjects*

We intend to recruit 12 subjects.

5) Study-Wide Recruitment Methods*

Patients with HS seen for their routine care at the Dermatology Outpatient Clinics at the University of Miami Hospital, South Miami satellite site, or Lennar Medical Foundation satellite site will be identified for possible study eligibility by any of the dermatologists in our practice. If the treating dermatologist is a study team member, they will ask the potential subject if they would be interested in being contacted by the study team to learn more about a research study for HS. A partial HIPAA waiver is needed, so that if the patient gives permission to be contacted, they will then be approached by a member of the study team while they are in clinic or if that is not feasible

then the treating dermatologist will ask if the patient would like to be contacted by telephone. If the treating dermatologist is not a study team member, they will ask the potential subject to contact the study team for more information by providing the study team's contact information and/or the study flyer. If the potential subject agrees to be contacted by the study team, the treating physician will ask the patient to sign a PHI release authorization form, so that the physician can provide the study team the patient's contact information. If it is then determined that they are interested in participating, they will be scheduled for a visit with the PI at our University of Miami Hospital dermatology clinic site where informed consent and all other study procedures will take place. The risks/benefits of the study will be presented to the subjects, as well as the disclaimer that refusal to participate in the study will in no way, shape, or form alter the type or quality of their care.

A partial HIPAA waiver is also needed as patients diagnosed with HS who signed the University of Miami's Consent to Contact consent during their routine medical care will be identified using research IT and URIDE. Each of those individuals with then be contacted by the phone by a study team member and asked if they would be interested in learning more about a research study on HS. If it is then determined that they are interested in participating, they will be scheduled for a visit with the PI at our University of Miami Hospital dermatology clinic site where informed consent and all other study procedures will take place. The risks/benefits of the study will be presented to the subjects, as well as the disclaimer that refusal to participate in the study will in no way, shape, or form alter the type or quality of their care.

6) Study Timelines*

We intend to enroll subjects over a one-year period from the date of IRB approval. Each subject will participate in the study for a total of 14 months. The initial portion of the study will be 8 weeks (V1 to V6; 56 days +/- 3) and the second portion of the study will 12 months after V6, and consists if 1 final visit at the 14 months (+/- 30 days) mark . Each subject will be invited for 7 visits: initial visit, follow up visits and a final visit.

7) Study Endpoints*

Primary endpoints

The primary endpoint of the study is the difference in healing rate between the treatment and control arms at 8 weeks.

Secondary endpoints

Secondary outcomes include:

- The difference in the average time to complete healing in days between the study arms
- The number of subjects with complete healing at each time point
- The number of subjects with nodule and/or tunnel recurrence at 8 weeks
- The difference in the average pain numeric scale at each time point between the two treatment groups
- The difference in the number of subjects with tenderness at surgical sites at each time point

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- Quality of post-surgical scar between sites
- Amount and quality of exudate at surgical site
- Range of motion difference between surgical sites
- Number of dressings used through to healing day
- Pain immediately after surgical procedure versus pain 24 hours post procedure
- Days of work lost
- HS Quality of Life and Dermatology Quality of Life Index (DQLI) change
- Overall cost per wound site (dressings used, pain medication used, days of work lost)
- Tissue analysis (biofilm, microbiome, immunohistochemistry analysis)

8) Procedures Involved*

After informed consent is obtained from each subject, they will be invited to participate in the study for 7 visits over a total of 14 months. The procedures involved are listed in the table of assessments

At the first visit, the surgical sites of interest will be identified, and a photo of the sites will be taken. The area in the bilateral axillae will be cleaned, then anesthetized using local anesthesia. Once the areas are properly anesthetized, a probe will be inserted into the tunnels to identify the terminal ends. An incision is then made along the probe and the tunnel exposed. All skin overlaying the tunnel and the base of the tunnel will then be removed and the wound edge beveled. Hemostasis will be achieved. Once hemostasis is achieved, a second picture will be taken of the surgical wounds. The initial area of the wounds will be measured. The bioelectric dressing with its hydrogel will then be applied to one surgical sites and a control dressing to the other based on a randomization sequence. The control dressing is the current standard of care which Vaseline and non-adherent gauze. A secondary absorbent dressing will then be applied as needed.

In the days between visits, the subjects will change the secondary dressings.

At each visit a focused physical exam will be performed. The corresponding HS-PGA (Table 1) and Hurley Stage (Table 2) will be calculated. The HS lesion locations will be marked on a HS Lesion Body Map (Table 3) and will also be photographed using standard photography

At each visit, the subject's pain on a visual analog scale, amount of pain medication used, number of dressings used, quality of life, and number of work/school days lost will also be quantified. Wound site exudate will be graded based on the Table 4 below. HS lesion erythema will be graded on the Clinical Erythema Assessment (CEA) scale (Table 5) at each visit. Active shoulder range of motion in degrees of the will be measured and recorded using a goniometer in the following directions: flexion, extension, and, abduction (Table 6)

At the first visit the excised tissue will be collected for tissue analysis in the laboratory. At visits 4 and 5, if the wound is not healed, the base of the wound will be debrided and the tissue sent for laboratory analysis. Additional debridement may occur during other visits based on the PI clinical judgment.

Data and specimens can be accessed by approved study personnel only.

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If the wounds heal within the 8 weeks visit (Visit 6), the subject will complete all visits and assessments and will then referred back to the referring physician for continued medica care. If the wound does not heal, the subject will be referred to their referring physician and will be offered follow up with the PI.

At the 14 months follow-up visit, subjects will undergo a physical examination of their scars at the healed surgical sites as part of the surgery performed in the study. Subjects will be asked about any recurrence in the areas treated (lesions at the surgical site, near the surgical site and/or elsewhere), satisfaction with the procedure and any procedure related adverse events. Scars will be evaluated using the Modified Vancouver Scar Scale (Table 7) and the observer portion of the Patient and Observer Scar Assessment Scale (POSAS) (Table 8). Patients will also be asked to fill the patient portion of the Patient and Observer Scar Assessment Scale POSAS (Table 8) and the Patient Scar Assessment Questionnaire, along with the quality-of-life questionnaires that were filled at previous visits. The scars at the surgical sites operated as part of the study will also be photographed using standard photography. A focused physical exam will be performed. The corresponding HS-PGA (Table 1) and Hurley Stage (Table 2) will be calculated. The HS lesion locations will be marked on a HS Lesion Body Map (Table 3) and will also be photographed using standard photography. In the event of recurrence at the surgical sites, HS lesion erythema will be graded on the Clinical Erythema Assessment (CEA) scale (Table 5) at each visit. Active shoulder range of motion in degrees of the will be measured and recorded using a goniometer in the following directions: flexion, extension, and abduction (Table 6).

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Table of Assessments

Week	0	0	1	2	4	8	14
Day	0	3	7	14	28	56	421
Visit	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Window (days)	0	±3	±3	±3	±3	±3	±30
Informed consent	X						
Eligibility	X						
Subject ID assignment	X						
Demographics	X						
HS history	X						
Medical history	X						
Concomitant medication	X	X	X	X	X	X	X
Physical exam (focused)	X	X	X	X	X	X	X
HS lesion map	X	X	X	X	X	X	X
Randomization	X						
HS lesion ultrasound	X					X	
Hurley stage	X	X	X	X	X	X	X
HS-PGA	X	X	X	X	X	X	X
Pain (VAS) -General	X	X	X	X	X	X	X
Pain (VAS) -surgical sites	X	X	X	X	X	X	X
Surgical site tenderness	X	X	X	X	X	X	X
Pain medication usage past 3 days	X	X	X	X	X	X	X
Wound area	X	X	X	X	X	X	
Scar assessment		X	X	X	X	X	X
Height	X					X	X
Body weight	X					X	X
Exudate	X	X	X	X	X	X	X
Erythema	X	X	X	X	X	X	X
Range of motion affected joint	X	X	X	X	X	X	X
Deroofing	X						
Product/SOC application	X	X	X	X	X	X	
Tissue collection	X			X	X		
QOL (DLQI)	X					X	X
Patient-reported scar assessment							X
Work/school days lost	X	X	X	X	X	X	X
Number of dressing used (per site)	X	X	X	X	X	X	
Photography	X	X	X	X	X	X	X
Ease of dressing application	X	X	X	X	X	X	
Adverse events	X	X	X	X	X	X	X

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Table 1: HS PGA Scale

Appendix Table 1. **Hidradenitis Suppurativa Physician's Global Assessment Scale**

Rating	Description
Clear	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and 0 noninflammatory nodules
Minimal	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and presence of noninflammatory nodules
Mild	0 abscesses, 0 draining fistulas, and 1–4 inflammatory nodules or 1 abscess or draining fistula and 0 inflammatory nodules
Moderate	0 abscesses, 0 draining fistulas, and ≥5 inflammatory nodules or 1 abscess or draining fistula and ≥1 inflammatory nodule or 2–5 abscesses or draining fistulas and <10 inflammatory nodules
Severe	2–5 abscesses or draining fistulas and ≥10 inflammatory nodules
Very severe	>5 abscesses or draining fistulas

Table 2: Hurley Score

Stage 1	Single or multiple abscesses without sinus tract formation or scarring
Stage 2	Recurrent abscesses with one or more sinus tracts and scarring widely separated by normal skin
Stage 3	Diffuse involvement with multiple sinus tracts and no intervening normal skin

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Table 3: Body Map

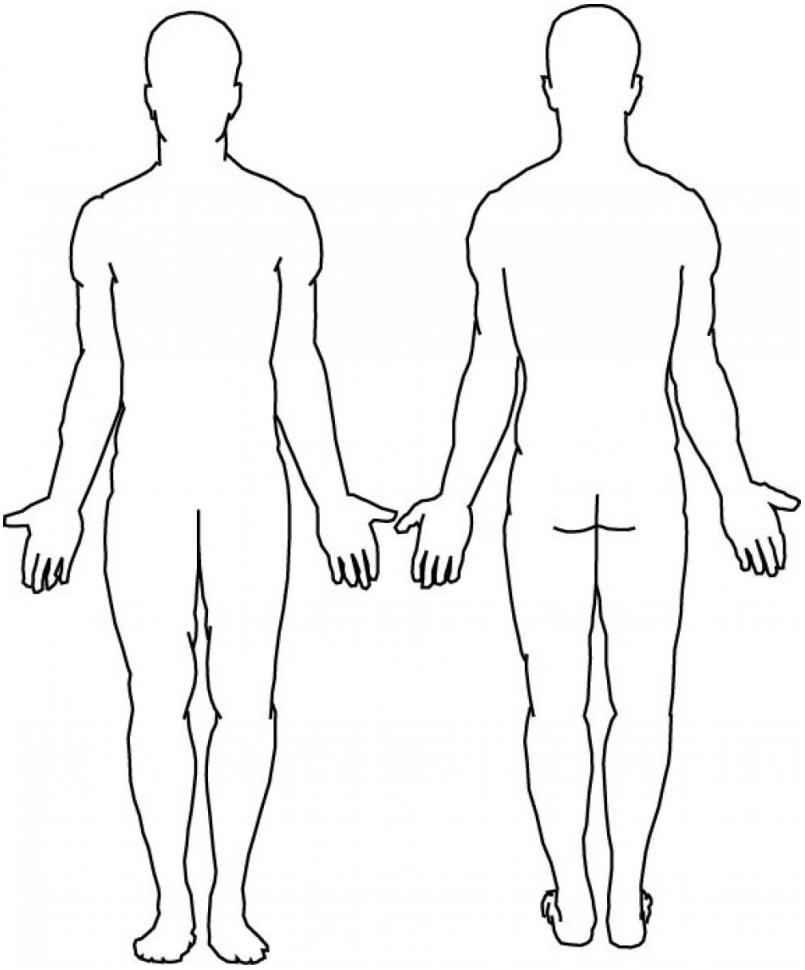

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Table 4: Exudate Evaluation

	Indicators		
Status	**Wound bed**	**Dressing**	**Surrounding skin**
Dry	Wound bed is dry; there is no visible moisture	Primary dressing is unmarked; dressing may be adherent to wound	Skin may be scaly, atrophic, hyperkeratotic
Moist	Small amounts of fluid are visible when dressing is removed; wound bed may appear glossy	Primary dressing may be lightly marked; dressing change frequency is appropriate	Skin is likely to be intact, hydrated, no lesions
Wet	Small amounts of fluid are visible when the dressing is removed	Primary dressing is extensively marked, but strikethrough does not occur; appropriate dressing change frequency	Initial fragmented areas of maceration may be apparent
Saturated	Free fluid is visible when the dressing is removed	Primary dressing is wet and strikethrough occurs; dressing change is required more frequently than usual	Peri-wound skin is likely to be macerated or denuded with extensive involvement
Leaking	Free fluid is visible when the dressing is removed	Dressings are saturated and exudate is escaping from primary and secondary dressings onto clothes or beyond; dressing change is required much more frequently than usual	Peri wound skin is likely to be macerated or denuded with extensive involvement

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Table 5: Clinician Erythema Assessment (CEA)

	CEA
0 = Clear	Clear skin with no signs of erythema
1 = Almost clear	Almost clear; slight redness
2 = Mild	Mild erythema, definite redness
3 = Moderate	Moderate erythema; marked redness
4 = Severe	Severe erythema; fiery redness

Table 6. Shoulder range of motion evaluation

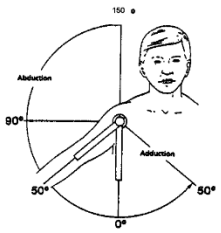
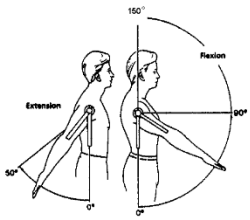
Shoulder Abduction and Adduction			Shoulder Flexion and Extension		
	Left			Left	
	Abduction 150°	Adduction 30°		Extension 50°	Flexion 150°
	Degrees	Degrees		Degrees	Degrees
	Right			Right	
	Abduction 150°	Adduction 30°		Extension 50°	Flexion 150°
	Degrees	Degrees		Degrees	Degrees

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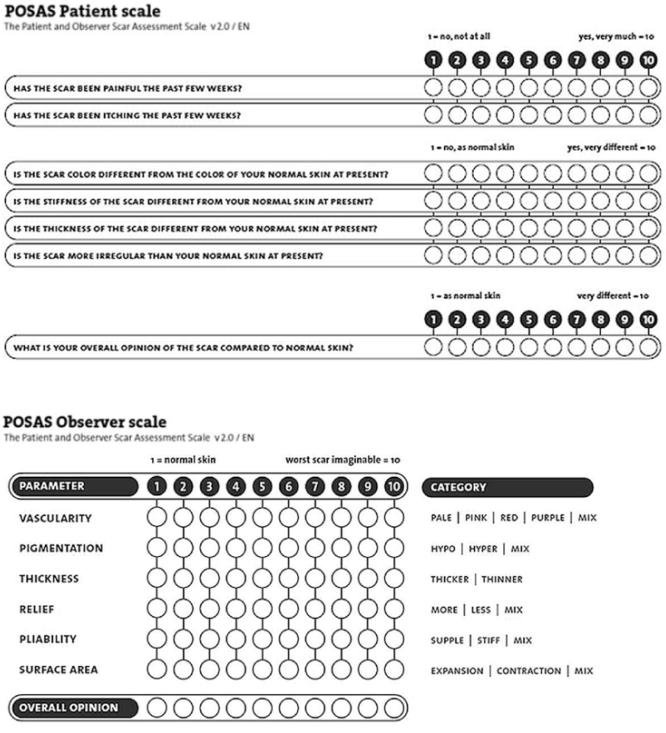
Table 7. Modified Vancouver Scar Scale

Skin characteristics	Parameters
Pliability	
0	Normal
1	Supple
2	Yielding
3	Firm
4	Ropes
5	Contracture
Height	
0	Flat
1	<2 mm
2	2–5 mm
3	>5 mm
Vascularity/erythema	
0	Normal
1	Pink
2	Red
3	Purple
Pigmentation	
0	Normal
1	Hypo-pigmented
2	Mixed
3	Hyper-pigmented

Table 8. The Patient and Observer Scar Assessment Scale POSAS



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9) Data and Specimen Banking*

Study records including informed consents and source documents will be stored in a locked cabinet in the Dermatology Clinical Trials Unit at University of Miami (University of Miami Hospital West Building, 1321 NW 14th St, Suites 504-508, 33136).

Collected samples will be assigned numeric identifiers (subject ID, visit and date of collection). Specimens will be banked for future use and kept under lock in the Pastar laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136).

All specimens will be stored at -80°C in the laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136).

10) Data and Specimen Management

Data collected will be analyzed by study staff. All study data will be saved on UM computers that are password protected. After initial data collection, all data analyses will be conducted in aggregates and will be de-identified.

11) Provisions to Monitor the Data to Ensure the Safety of Subjects*

This study involves procedures that are within the standard care spectrum for HS. However, the safety of subjects is the primary objective of the PI and the study staff. All subjects will be evaluated for adverse events routinely at every study visit. PI and study staff will actively solicit relevant adverse events. Subjects will also be provided with contact information and encouraged to contact PI and study staff with any concern or emerging adverse event. Since this is small, unblinded study, a data monitoring committee is not required.

Data recorded in the subject's CRF will be reviewed for specific adverse event including: pain, fever, chills, bleeding, burning or discomfort from product application. Since all procedures conducted are within the scope of standard care, we do not expect significant adverse events above and beyond the usual events associated with minimally invasive surgical procedure (i.e. incision and drainage). However, if a subject dies or experiences admission to the hospital due to adverse event that is involving the treatment site or any serious adverse event that is directly related to the study procedure, the PI will pause the study for assessment and decide if to continue the study.

12) Withdrawal of Subjects

Although unlikely, a subject may withdraw from the study at any time at their own request. Subjects may also be withdrawn at any time at the discretion of the PI due to concerns about safety, behavioral, compliance, or administrative reasons.

At the time of discontinuing from the study, visit 6 relevant assessments will be conducted. Subjects will be questioned regarding their reason for withdrawal and reasons will documented in the CRF. If the subject withdraws from the study and also withdraws consent (see below) for disclosure of future information, no further evaluations will be performed, and no additional data will be collected. The PI may retain and continue to use any data collected before such withdrawal

of consent. If a subject withdraws from the study due a SAE, the SAE will be recorded in the CRF and reported to the IRB. Lack of completion of all or any of the withdrawal/early termination procedures will not be viewed as protocol deviations so long as the participant's safety was preserved.

Withdrawal of Consent:

Subjects who request to discontinue receipt of study treatment will remain in the study and must continue to be followed per protocol. The only exception to this will be when a subject specifically withdraws consent for any further contact. Subjects should notify the PI or staff of the decision to withdraw consent from future follow-up and this will be recorded in the CRF. The withdrawal of consent should be explained in detail in the CRF, as to whether the withdrawal is only from further receipt of treatments or also from study procedures and/or posttreatment study follow-up.

13) Risks to Subjects*

The procedures involved in the study are within the standard care for people with HS and are indicated. Therefore, the main added risk we anticipate is unintentional reveal of PHI.

Additional risks that are inherent in the standard care treatment include: pain, bleeding, infection and abnormal scarring that are related to the surgical procedures. There are minimal risks associated with the use of the bioelectric and control dressing that include rash, stinging or burning at the application site.

14) Potential Benefits to Subjects*

Regardless of the research outcomes, the patients will benefit from immediate symptom relief. They will also have better healing of the lesions. They may also experience no recurrence in the areas treated. If our hypothesis is correct, they will be spared worsening of disease. Given the poor overall management of HS nationwide, patients will benefit from care at an expert medical center. Patients will also have access to free dressing and wound care for the duration of the study which are infrequently covered for HS.

15) Vulnerable Populations*

This research study does not include vulnerable populations. Specifically, we will not enroll minors, pregnant women, prisoners, or cognitively impaired people.

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16) Multi-Site Research*

This is a single site study.

17) Community-Based Participatory Research*

This study was designed without CBPR.

18) Sharing of Results with Subjects*

There are no results to share with the subjects.

19) Setting

Clinical study activities will take place in the Dermatology Clinical Trials Unit at University of Miami (University of Miami Hospital West Building, 1321 NW 14th St, Suites 504-507, 33136) and the Dermatology clinic at UMH (1295 NW 14th St suite K/L/M, Miami, FL 33125).
Laboratory analysis activities will take place in the Pastar laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136). All specimens will be stored at -80°C in the laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136).

This study is open to all eligible subjects. Recruitment efforts will focus on the existing dermatology clinics with the University of Miami Health System as well as other specialty clinics at UMHS where HS subjects may visit such as general surgery, plastic surgery and gynecology.

20) Resources Available

Dr. Lev-Tov (PI) is a board-certified dermatologist with extensive experience in treating people with HS and the study related procedures. He has conducted many clinical trials and is considered a leader in the field. Dr. Pastar (co-PI) is an associate professor at UM and well recognized expert in the field of wound healing. She has conducted many similar studies and has all the expertise and equipment needed to conduct the work related to this study.

Both Dr. Lev-Tov and Dr. Pastar will personally train all study staff on the procedures related to the protocol. All study team members will also complete the necessary CITI training modules.

Prior Approvals

No prior approvals are needed.

21) Local Number of Subjects

We plan to complete the study on 12 subjects. Given the usual attrition rate we will plan to consent up to 15 subjects.

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22) Confidentiality

The research team will keep all study information and samples in a locked office and laboratory under password protection while the database is maintained. All data and specimens will be de-identified and coded as described earlier. The data will be only accessible by the research team.

Local transport of study specimens will be done in a sealed biohazard bag within a secondary container with a secured lid.

Choose the statements below that are applicable to this research:

26(a). Will the research collect protected health information or personally identifiable information from the EMR or from subjects at UHealth and/or JHS?

☒ Yes (If checked go to 26(b))

☐ No (If checked, go to Section 27)

26(b). Check the box next to the correct statement below

☒ Research Subjects will sign a HIPAA Authorization before the research will collect this data.

☐ Research Subjects will not sign a HIPAA Authorization for this data collection and the research is requesting a waiver of HIPAA authorization from the IRB.

26(c). How will the research store the data?

☒ On a University of Miami electronic device (e.g. encrypted, password-protected computer)

☐ On a cloud-based storage system that is approved by the University of Miami

☐ On the secured JHS SharePoint environment.

☐ Other, specify: Click here to enter text.

26(d) Select one of the following:

☐ The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that does not include any indirect or direct identifiers (listed in the instructions for Section 26 of this protocol), and the recorded data will not be linked to the individual's' identity.

OR

☒ The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions for Section 26 of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject's identity. The link to each subject's identity and/ or other identifiable information will be maintained on a document separate from the research data.

26(e) Additional requirement for Jackson Health System Data:

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☒ Not-applicable, no data will be acquired from JHS under a waiver of authorization.

☐ JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research under a waiver of authorization shall only be stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions for Section 26 of this protocol.

23) Biospecimens

☐ Not applicable. No biospecimens will be collected

☐ *Bio*-Specimens obtained for this research will be stored without any direct or indirect identifiers.

☒ *Bio*-Specimens obtained for this research will be stored in a de-identified coded manner.

When required to transport data or bio-specimens for this research, the research team will transport the data and bio-specimens in a de-identified (or anonymous) manner with a link to the individual subject's identity maintain separately from the data and/or bio-specimen.

24) Provisions to Protect the Privacy Interests of Subjects

Study subjects will only be asked to provide personal information to approved study personnel, who will ensure the subject is at ease with the situation. Study personnel will clearly explain that the subject does not have to answer any questions or provide any sample they are uncomfortable about.

Compensation for Research-Related Injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Provide a copy of contract language, if any, relevant to compensation for research-related injury.

25) Economic Burden to Subjects

The study subjects will not have to pay for any procedure involved in the research study.

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26) Consent Process

The research team will follow the "HRP-090 SOP: Informed Consent Process for Research" to obtain informed consent and the "HRP-091 SOP: Written Documentation of Informed Consent" to document informed consent in writing.

The consent and assent will be translated into Spanish for the inclusion of non-English Spanish speakers.

Study personnel will meet with each potential subject to discuss the study in detail, answer questions, and allow the subject to read the entire consent form. The informed consent form explicitly states the rationale for the study and requirements for participation, both before and during the session. The informed consent form states that subjects may discontinue participation or be terminated from the study at any time.

All pertinent aspects of the study will be explained to the subject before he or she signs the informed consent form. A signed informed consent form will be obtained from the subject before any activity is undertaken as part of the study.

Process to Document Consent in Writing

The research team will follow the "HRP--091 SOP: Written Documentation of Informed Consent" to document informed consent in writing.

27) Authorization for Use and Disclosure of Protected Health Information (HIPAA)

Type of Request:

☒ Waiver of Authorization for access to medical record for subject identification/recruitment.

☐ Waiver of Authorization for access to medical record to obtain data for the research.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

28) Drugs or Devices

All drugs and devices used in the study will be used in a manner consistent with routine clinical practice and "per label". The main study intervention is the use of a dressing marketed

under the name Procellera. Procellera has been cleared by the FDA for treatment of wounds (see FDA 510 (K) marketing approval letter attached) and will be used “per label” and routine clinical practice.

29) References

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