Clinical Trial Protocol: Hydroprep Wound Therapy and Motion NPWT for Chronic Lower Extremity Wounds

Study Title: A Prospective, Open-Label, Single-Arm Clinical Trial Evaluating the Efficacy of Hydroprep Wound Therapy Followed by Motion Negative Pressure Wound Therapy in the Treatment of Chronic Lower Extremity Wounds
Protocol Version: 1.0

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Sponsor: MedAxis

Clinical Trial Sites:

1. West Boca Center for Wound Healing, 4855 W. Hillsboro Blvd. Ste B6, Coconut Creek, FL 33073

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1. Introduction and Background

Chronic lower extremity wounds represent a significant and growing public health challenge in the United States, imposing a substantial clinical and economic burden. Affecting millions of Americans annually, chronic wounds are estimated to impact approximately 2.5% of the total U.S. population, with prevalence rates rising, particularly among Medicare beneficiaries where it increased from 14.5% in 2014 to 16.4% in 2019, representing an increase from 8.2 million to 10.5 million individuals. The financial implications are staggering, with annual cost estimates for managing chronic wounds ranging broadly from $22.5 billion to over $96.8 billion, depending on the scope of the analysis and inclusion of secondary diagnoses. These substantial costs are driven by prolonged treatment regimens, frequent hospitalizations, and the complex nature of underlying comorbidities. Effective wound bed preparation and sustained wound healing are therefore crucial not only for improving patient quality of life but also for mitigating the escalating healthcare expenditures. Hydroprep Wound Therapy (Medaxis) offers a novel approach to wound bed preparation, utilizing a highly energized fluid jet to remove non-viable tissue, biofilm, and reduce bacterial load, while stimulating the wound bed. Following wound bed preparation, Negative Pressure Wound Therapy (NPWT), such as the Motion® System, is widely recognized for promoting wound healing by removing exudate, reducing edema, increasing blood flow, and promoting granulation tissue formation. This trial aims to evaluate the combined efficacy of these two modalities in a cohort of patients with chronic lower extremity wounds, seeking to provide data for an improved and more cost-effective treatment strategy.

2. Objectives

Primary Endpoint:

- **Percent Area Reduction (PAR):** To assess the percentage reduction in wound surface area from baseline to week 4.
- **Weeks to Cessation of NPWT:** To determine the median time (in weeks) required for wound closure sufficient to cease NPWT application.
- **"Graft-Ready":** Time for investigator from study initiation to decision to begin closure procedure, graft or CAMP/CTP application process.
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Secondary Endpoints:

- Incidence of wound infection.
- Pain assessment (VAS scale) at each visit.
- Time to complete wound closure (defined as 100% re-epithelialization).
- Quality of life (e.g., using a validated wound-specific questionnaire).
- Number of Hydroprep treatments required.
- Adverse events related to Hydroprep or Motion NPWT.
- Cosmetic outcome (investigator and patient assessment at 3 months post-closure).

3. Study Design

This will be a prospective, open-label, single-arm clinical trial involving 20 patients with chronic lower extremity wounds. Each patient will serve as their own control for wound healing progression. The study duration for each patient will be 4 weeks of active treatment with follow-up until wound closure or 12 weeks, whichever comes first.

4. Study Population

Total N: A Minimum of 20 patients to a maximum of 50 patients shall be recruited for this pilot study.

Inclusion Criteria:

- Patients of all ages (including minors, with appropriate parental/guardian consent and assent if applicable).
- Chronic lower extremity wound (e.g., venous leg ulcers, arterial ulcers, diabetic foot ulcers, pressure injuries, traumatic wounds) present for at least 4 weeks prior to enrollment.
- Wound size less than or equal to 36 cm^2.
- Wound has been non-progressive (less than 20% area reduction) for at least 4 weeks prior to enrollment, despite standard of care.
- Adequate circulation to the affected limb, as determined by an Ankle-Brachial Index (ABI) between 0.7 and 1.3, or a toe-brachial index (TBI) > 0.6 if ABI is unreliable, or transcutaneous oxygen measurement (TCOM) ≥ 30 mmHg (if applicable based on wound etiology) or StO_2 greater than 60% as measured by NIRS.

- Ability and willingness of the patient or caregiver to comply with study procedures, including regular clinic visits and home care instructions.
- Signed informed consent by the patient or legally authorized representative.

Exclusion Criteria (similar to published DFU trials):

- Wound exhibiting signs of acute infection (e.g., cellulitis, purulence, fever) requiring systemic antibiotics at baseline (patients can be screened after infection resolution).
- Untreated osteomyelitis.
- Non-enteric and unexplored fistulas in the wound area.
- Malignancy in the wound or history of malignancy within the wound bed.
- Exposed vasculature, nerves, anastomotic sites, or organs within the wound.
- Wound due to an active autoimmune disease requiring systemic immunosuppression (e.g., systemic corticosteroids >10 mg daily dose) or cytotoxic chemotherapy.
- Known contraindications to Hydroprep Wound Therapy (e.g., open injuries to blood vessels, unprotected neurovascular structures, eyes, ears, nose, delicate vessels) or Motion® NPWT (e.g., untreated osteomyelitis, exposed blood vessels/organs/nerves, un-debrided necrotic tissue).
- Concurrent participation in another clinical trial involving an investigational drug or device that would interfere with this study.
- Known allergies to any components of the Hydroprep or Motion NPWT systems.
- Pregnant or breastfeeding women.
- Life expectancy less than 1 year.
- Significant uncontrolled medical disorders (e.g., severe cardiovascular, renal, hepatic, or pulmonary disease, uncontrolled diabetes (HbA1c > 12%)).
- Previous treatment of the index ulcer with tissue-engineered materials or other scaffold materials within the last 30 days.
- Affected extremity requiring hyperbaric oxygen therapy during the trial or within 2 weeks of enrollment.
- Patient or caregiver unable to manage the Motion NPWT device.

5. Study Procedures

Screening (Week -1 to Day 0):

- Informed consent process.
- Medical history and physical examination.
- Wound assessment: digital photography, tracings for surface area measurement (cm^2), depth measurement (cm), presence of exudate, wound bed characteristics, periwound skin assessment.

- Baseline pain assessment (VAS).
- Assessment of circulation (ABI/TBI/TCOM as appropriate).
- HbA1c for diabetic patients.
- Blood work (CBC, CMP) if clinically indicated.

Treatment Phase (Weeks 1-4):

- **Hydroprep Wound Therapy:** Patients will undergo Hydroprep Wound Therapy with normal saline twice weekly for 4 weeks. Each session will involve debridement of non-viable tissue and stimulation of the wound bed as per manufacturer's guidelines.
- **Motion Negative Pressure Wound Therapy:** Immediately following Hydroprep debridement, the Motion® NPWT system will be applied to the wound. NPWT will be applied continuously between Hydroprep treatments. Dressing changes will occur every 48-72 hours, or more frequently if clinically indicated (e.g., for infected wounds). Pressure settings will be clinician-determined based on wound characteristics and patient tolerance, typically between -80 mmHg and -125 mmHg.
- **Concomitant Care:** Standard wound care principles, including offloading (if applicable), infection management, and dressing changes, will be maintained.

Assessments (Weekly during treatment, then follow-up):

- **Weekly:** Wound assessment (digital photography, tracing for surface area, depth measurement, exudate, wound bed, periwound), pain assessment (VAS), assessment of NPWT compliance and function, adverse event reporting.
- **Week 4:** Final Hydroprep treatment. Comprehensive wound assessment. Transition to follow-up or sub-protocol as described below.
- **Follow-up (until closure or 12 weeks):** Wound assessment every 2 weeks from Week 4 to Closure or Week 12 (digital photography, tracing for surface area, depth), pain assessment (VAS), adverse event reporting.

Sub-Protocol: Wound Depth < 0.1 cm (Closure Phase):

Once the wound depth reaches ≤ 0.1 cm, and the wound bed is adequately granulated and free of infection, the investigator will have the option to transition to their choice of definitive wound closure. This may include:

- **Split-Thickness Skin Graft (STSG):** Standard surgical application of an autologous STSG.
- **Cellular and/or Acellular Matrix Product (CAMP):** Application of a commercially available cellular or acellular matrix product of the investigator's choice, applied according to manufacturer's instructions for use.
- The decision for STSG or CAMP will be documented, including rationale. Patients will continue to be followed for wound closure.

6. Data Collection and Management

- Case Report Forms (CRFs) will be used to collect all study data.

- Data will be entered into a secure, electronic database.
- Regular data monitoring will be conducted to ensure accuracy and completeness.
- Wound measurements will be independently reviewed (e.g., by blinded assessor or central image analysis) to minimize bias.

7. Statistical Considerations

- **Sample Size:** A minimum of 20 patients with a maximum of 50 patients chosen for this pilot study to assess feasibility and gather preliminary efficacy data for future larger trials.
- **Primary Endpoints Analysis:**
  - **Percent Volume Reduction (PAR):** Calculated as ((Baseline Volume−Week 4 Volume) / Baseline Volume) × 100%. Descriptive statistics (mean, standard deviation, median, range) will be used.
  - **Weeks to Cessation of NPWT:** Median and interquartile range will be reported. Kaplan-Meier survival analysis may be used if appropriate.
- **Secondary Endpoints Analysis:** Descriptive statistics will be used for all secondary endpoints. Paired t-tests or non-parametric equivalents may be used to compare pre and post-treatment measures where appropriate (e.g., pain).
- **Safety Analysis:** All adverse events will be summarized by frequency, severity, and relatedness to the study interventions.

8. Ethical Considerations

- The study will be conducted in accordance with the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines, and all applicable local and federal regulations.
- Institutional Review Board (IRB) approval will be obtained from all participating sites prior to patient enrollment.
- Written informed consent will be obtained from all participants or their legally authorized representatives. For minors, assent will be obtained in addition to parental/guardian consent, as per IRB guidelines.
- Patient confidentiality will be maintained at all times.
- Data Safety Monitoring Plan: A plan will be in place for monitoring adverse events and ensuring patient safety throughout the trial. Serious Adverse Events (SAEs) will be reported to the IRB and sponsor (if applicable) within 24 hours.

9. Investigator's Responsibilities

- Adherence to the study protocol.
- Ensuring patient safety and well-being.
- Accurate and timely data collection.
- Reporting of adverse events.
- Maintaining study records.

IRB Approval Documentation Requirements (General Guide)

For each site, the following documents will be prepared and submitted for IRB review:

1. **IRB Application Form:** Completed application specific to each institution's IRB.
2. **Clinical Trial Protocol:** The detailed protocol as outlined above.
3. **Informed Consent Form (ICF):** A comprehensive document outlining the study purpose, procedures, risks, benefits, alternatives, confidentiality, and participant rights. (See template below)
4. **Assent Form (for minors, if applicable):** Age-appropriate forms for children to agree to participate.
5. **Patient Recruitment Materials:** Flyers, advertisements, or scripts for recruitment (See template below).
6. **Investigator's Brochure/Device Manuals:**
    - Medaxis Hydroprep Wound Therapy system: Product information, indications, contraindications, warnings, precautions, and any relevant clinical data.
    - Medela Invia Motion® Negative Pressure Wound Therapy System: Product information, indications, contraindications, warnings, precautions, and instructions for use.
7. **Investigator(s) Curriculum Vitae (CVs):** For all investigators and key study personnel.
8. **Site-Specific Documents:**
    - Site-specific budget (if applicable).
    - Institutional policies relevant to clinical research.
    - Conflict of Interest disclosures for all study personnel.
    - Proof of Human Subjects Research Training (e.g., CITI Program certification).
9. **Data Safety Monitoring Plan (DSMP):** Outline for monitoring safety data and adverse events.
10. **HIPAA Authorization Form:** For the use and disclosure of Protected Health Information (PHI).
11. **Any other documents required by the specific IRB.**

Sample Informed Consent Form (ICF) Template

Study Title: A Prospective, Open-Label, Single-Arm Clinical Trial Evaluating the Efficacy of Hydroprep Wound Therapy Followed by Motion Negative Pressure Wound Therapy in the Treatment of Chronic Lower Extremity Wounds

Investigator: [Lead Investigator Name, MD]

Institution: [Site Name]

Contact Phone: [Phone Number]

Introduction

You are being asked to participate in a research study. This form explains the study, its risks, benefits, and your rights as a participant. Please read it carefully and ask any questions you have. Participation is voluntary. You can decide not to participate or withdraw at any time, even after agreeing, without affecting your medical care.

Why is this Study Being Done?

You are being asked to participate because you have a chronic wound on your lower extremity that has not healed with standard treatments. We are studying a new approach to wound care that combines two methods: the Hydroprep Wound Therapy system, which cleans and prepares the wound bed, and the Motion Negative Pressure Wound Therapy (NPWT) system, which helps promote wound healing. We want to see how effective this combined approach is in helping chronic lower extremity wounds heal.

How Many People Will Participate?

Approximately 20 to 50 people will participate in this study across all sites.

What Will Happen During the Study?

If you agree to participate:

1. **Screening (Week -1 to Day 0):**
    - We will review your medical history and perform a physical exam.
    - We will examine your wound, take pictures, and measure its size and depth.
    - We will ask about your pain level.
    - We may perform tests to check the blood flow in your leg (e.g., ABI, TBI, TCOM).
    - If you have diabetes, we will check your HbA1c level.
    - We may take blood samples if needed for your routine care.
2. **Treatment Phase (Weeks 1-4):**
    - You will receive Hydroprep Wound Therapy twice a week for 4 weeks. This involves using a specialized device to clean your wound with a gentle fluid jet.

- Immediately after each Hydroprep treatment, the Motion Negative Pressure Wound Therapy (NPWT) system will be applied to your wound. This system uses a vacuum to help draw fluid away from the wound and promote healing. You will wear this device continuously between your Hydroprep treatments.
- The NPWT dressing will be changed every 2-3 days, or more often if necessary.
- You will continue to receive other standard wound care as advised by your doctor (e.g., offloading, infection treatment).
- We will assess your wound, pain, and check the NPWT device weekly.

3. **Wound Closure Phase (After Week 4, if applicable):**
   - If your wound has significantly healed (depth ≤ 0.1 cm) after the 4 weeks of Hydroprep and NPWT, your doctor may decide to close the wound with either a Split-Thickness Skin Graft (STSG) or a Cellular and/or Acellular Matrix Product (CAMP). Your doctor will discuss the best option for your wound.
   - You will continue to be followed until your wound is completely closed or for up to 12 weeks, whichever comes first.
4. **Follow-up:**
   - We will continue to assess your wound every 2 weeks until it is completely closed or for a maximum of 12 weeks from the start of the study.
   - We will also assess your pain and collect information on any side effects you experience.
   - At 3 months after your wound closes, we will assess the cosmetic outcome of the wound.

What are the Risks and Discomforts?

- **Hydroprep Wound Therapy:** Mild pain or discomfort during the procedure, bleeding, temporary redness around the wound. Rare risks include damage to healthy tissue if not used correctly.
- **Motion Negative Pressure Wound Therapy:** Pain or discomfort, skin irritation around the dressing, bleeding, infection, allergic reaction to dressings, technical issues with the pump (e.g., alarms, battery failure). Rare risks include bleeding, tissue adherence to the dressing, or damage to vital structures if improperly applied.
- **Wound Closure Procedures (STSG/CAMP) (if applicable):** Risks associated with surgical procedures, including pain, bleeding, infection, scarring, graft/product failure, donor site complications (for STSG).
- **General Risks:** Discomfort during wound assessments, potential for delayed wound healing, risk of infection (which can occur with any wound), privacy breach (though measures are in place to protect your information).

We will do our best to minimize these risks. Please tell the study staff immediately if you experience any discomfort or problems.

What are the Potential Benefits?

- You may experience improved wound healing, potentially leading to faster closure of your chronic wound.
- Your pain may be reduced.
- You will receive close monitoring of your wound by wound care specialists.
- The information gained from this study may help improve treatment for other patients with chronic wounds in the future.

Are There Alternatives to Participation?

Yes, you have other options for treating your chronic wound, including:

- Standard wound care alone (e.g., dressings, debridement without Hydroprep, offloading).
- Other types of wound debridement (e.g., sharp debridement, enzymatic debridement).
- Other NPWT systems.
- Surgical interventions not included in this study.
- No treatment.

Your doctor will discuss these alternatives with you.

Confidentiality

Your privacy will be protected. Your name and other identifying information will not be shared in any reports or publications. Your study data will be assigned a unique code number. Only authorized study personnel will have access to your identifiable records. Your medical records and study data may be reviewed by the Institutional Review Board (IRB), regulatory agencies (e.g., FDA), and the study sponsor (if applicable) to ensure the study is conducted properly.

Costs

The Hydroprep Wound Therapy treatments and the Motion NPWT system and associated dressings provided specifically for this study will be covered by the study. You or your insurance will be responsible for the costs of your regular medical care, physician visits, and any additional treatments or medications not directly related to the study. If you receive a skin graft or matrix product, those costs will be billed to your insurance or be your responsibility, as per standard practice.

Compensation

You will eceive financial compensation for participating in this study.

Voluntary Participation and Withdrawal

Your decision to participate is entirely voluntary. You can withdraw from the study at any time without penalty or loss of medical care. If you withdraw, your existing study data will still be used, but no new data will be collected from you.

Questions?

If you have any questions about the study, please contact [Lead Investigator Name] at [Phone Number].

If you have questions about your rights as a research participant, please contact the [Site Name] Institutional Review Board at [IRB Phone Number/Email].

Signature
I have read and understand this consent form. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study.

Participant's Name (Printed)

Participant's Signature

Date

Signature of Person Obtaining Consent

Date
