Clinical Investigational Plan

Evaluation of Conventional and Long Pulse Widths During a Temporary Spinal Cord Stimulation Trial

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1. STUDY SUMMARY

Sponsor Contact Information	Ohio Pain Clinic Amol Soin, MD 7076 Corporate Way Dayton, OH 45458
Study Purpose	The purpose of this study is to evaluate the effect of pulse widths <500 µS and >1000 µS on clinical outcomes during a temporary SCS trial.
Study Design and Scope	The proposed study is a prospective, single-center, two arm, randomized, crossover design to be conducted at The Ohio Pain Clinic. The study will enroll up to 15 subjects in order to include up to 10 subjects in the study. Subjects selected to participate in the trial have back and/or leg pain, have been evaluated as a candidate for SCS and have agreed to undergo a temporary SCS trial using the Algostim system with percutaneous leads. Each subject will be followed during the trial period of approximately 7 days. The study will end when the last subject has completed the trial period. exited. The expected enrollment period for this study is approximately three months. After exit from the clinical study, subjects will continue to be followed by their physician per usual care. All device and procedure-related AEs will be collected and reported per the study protocol.
Primary Effectiveness Objective	Compare the change from baseline of pain scores between the two study arms. Pain scores are obtained using the Numeric Rating Score (NRS) administered at baseline and after completion of each arm of the study.
Secondary Effectiveness Objectives	Secondary measures of therapy effectiveness will include: • Paresthesia distribution: At end of each arm, subjects will be asked to complete a diagram that shows distribution of paresthesia. • At the end of the trial period, subjects will be asked to select their favorite program. • At the end of the trial period, subjects will be asked to rate the quality of the pain relief achieved during the trial (from either arm) using the following scale*; Excellent, Very Good, Good, Fair or Poor.* • At the end of the trial period, subjects will be asked to rate their overall satisfaction with the pain relief achieved during the trial (from either arm) using the following scale: *Very Satisfied, Satisfied, Neither Satisfied nor Unsatisfied, Unsatisfied, or Very Unsatisfied.* • Number of patients who achieved ≥ 50% pain relief during the trial (from either arm)
Secondary Safety Objectives	Secondary measures of therapy safety will include: • Rate of device-related and/or procedure-related AEs from the Trial procedure through study completion.

Study Procedures	After the subject has consented to the study, he or she will be enrolled in the clinical study and undergo a baseline evaluation. The patient will then be randomly assigned to arm one (pulse with <500 μS) or arm two (pulse width >1000 μS) and undergo an Algovita trial procedures. Following the trial procedure, the subject's EPG will be set to the appropriate pulse width, based on the arm assigned, and then programmed to achieve optimal pain relief. For the next three days, the subject will evaluate pain relief generated by the 1st assigned program (arms). After 3 days, the patient will visit the Ohio Pain Clinic for data collection and then reprogramming of the EPG for the next arm. For the next three days, the subject will evaluate the SCS therapy generated by the 2nd assigned program and then return to the clinic for data collection, removal of the leads and exit from the study. After the subject is exited from the study, he or she will be followed by the Ohio Pain Clinic per usual care. The data collection requirements are listed below. **Enrollment:** • Informed consent signed • Confirmation of study eligibility **Baseline evaluation:** • Relevant medical history • Physical examination • Brief Pain Inventory • Demographics • Record pain ratings and pain map **After the lead implantation:** • Implant procedure • Document SCS products & lead configuration, electrode position and programmed parameters **4 and 7 day (+/– 2) Post-Implantation:** • Record pain rating for current arm • Record paresthesia and pain map for current arm • Document AEs • Program subject with next arm parameters and document **Study Exit** • Record pain rating for current arm • Record paresthesia and pain map for current arm • Record program preference • Record satisfaction and pain relief from each program • Document study exit reason & AEs

1. STUDY DESIGN

The proposed study is a prospective, single-center, two arm, randomized, crossover design to be conducted at The Ohio Pain Clinic. The study will enroll up to 15 subjects in order to include up to 10 subjects in the study. Subjects selected to participate in the trial have back and/or leg pain, have been identified as a candidate for SCS and have agreed to undergo a temporary SCS trial using the Algostim system with percutaneous leads. Each subject will be followed during the trial period of approximately 7 days.

The study will end when the last subject has completed the trial period or is exited. The expected enrollment period for this study is approximately three months. After exit from the clinical study, subjects will continue to be followed by their physician per usual care. All device and procedure-related AEs will be collected and reported per the study protocol.

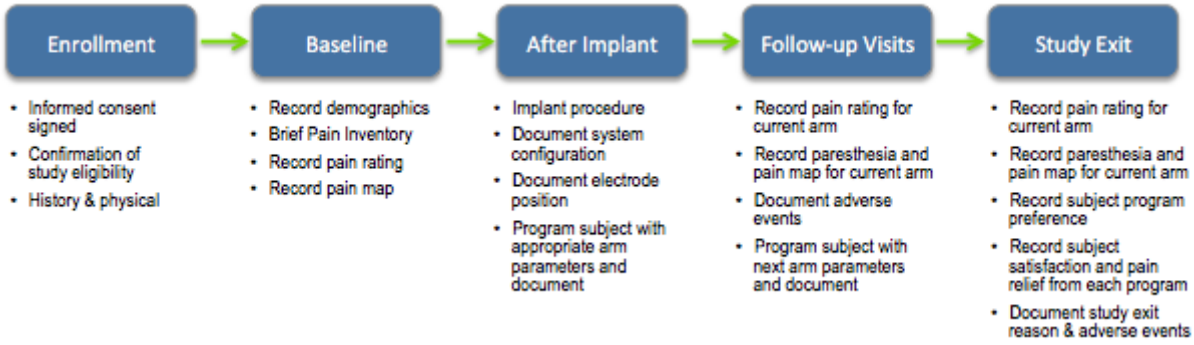

Figure 6-1: Algovita SCS Post-Market Clinical Study Design

1.1 OVERVIEW OF DATA COLLECTION AT STUDY VISITS

Enrolled subjects will have up to 5 scheduled visits as follows: Enrollment, Baseline, Implant, Follow-up at 4 and 7 days (+/–2) post implantation and a Study Exit visit as shown in Table 6.1.

Assessments and Data Collection	Enrollment	Baseline	After Implant	Follow-up Visits	Study Exit
• Eligibility confirmation	✓				
• Medical history • Physical exam	✓				
• Informed Consent	✓				
• Record demographics • Brief Pain Inventory • Record pain map		✓			
• Implant and System information			✓		
• Record pain rating for current arm • Record paresthesia and pain map for current arm • Document any AEs				✓	✓
• Record subject program preference • Record subject satisfaction and pain relief from each program • Document study exit reason & any AEs					✓

Table 6-1: Summary of Assessments at Each Visit

2. STUDY PROCEDURES

2.1 DATA COLLECTION REQUIREMENTS

Subject data will be collected and documented on case report forms (CRFs). Drafts of the CRFs for this study are located in Appendix 17.

2.1.1 Subject Screening Procedure

Subjects will be screened from candidates for SCS, that have agreed to undergo an SCS temporary trial and that meet study eligibility. Subjects who meet this criteria will be asked to participate in the study and if they agree will be required to sign an informed consent prior to any study-related procedures or data collection occurring.

Assessments and Data Collection	Enrollment	Baseline	After Implant	Follow-up Visits	Study Exit
• Eligibility	✓				
• Medical history • Physical exam	✓				

• Informed Consent	✓				
• Record demographics • Brief Pain Inventory • Record pain map		✓			
• Implant and System information			✓		
• Record pain rating for current arm • Record paresthesia and pain map for current arm • Document any AEs				✓	✓
• Record subject program preference • Record subject satisfaction and pain relief from each program • Document study exit reason & any AEs					✓

Table 6-1: Summary of Assessments at Each Visit