Cover letter for NCT03328143
Protocol ID 17.101
Protocol title Feasibility of Aromatherapy in an Awake Craniotomy Environment
Date: November 21, 2020

The document listed as Protocol Synopsis reflects the full Study Protocol and Statistical Analysis Plan. As this was a feasibility study, we did not prepare a formal study protocol or statistical analysis plan.

Thank you,

Richard A Rovin, MD

Protocol Summary

Title	A Feasibility Study of Lavender Aromatherapy in an Awake Craniotomy Environment
Principal Investigator	Richard A Rovin, MD
Research Question(s)	Is it possible to utilize lavender aromatherapy during awake craniotomy
Study Aims and Hypotheses	H_0: Aromatherapy is technically feasible during awake neurosurgical procedures Aim 1: To determine the percent of patients who would consent to participate Aim2: To determine the study completion rate for the consented patients
Primary Endpoint(s)	1. The number of patients consenting to participate 2. The number of patients completing the study
Secondary Endpoint(s)	1. Anxiety before and after lavender aromatherapy intervention 2. Pain before and after lavender aromatherapy intervention 3. Patient's expectation of lavender aromatherapy 4. Patient satisfaction with lavender aromatherapy
Study Design	Open label, single arm
Study Population	**Inclusion Criteria:** an adult patient undergoing clinically indicated cranial neurosurgical procedure **Exclusion Criteria:** allergy to lavender (Lavandula angustifolia); aversion to lavender scent; history of asthma or COPD; pregnancy; history of contact dermatitis following exposure to cosmetic fragrances
Treatment	Inhalation of lavender from a nasal inhaler, prior to the start of surgery and every 30 minutes thereafter, or if requested by the patient
Method of Randomization	N/A
Sample Size Calculation	N/A
Outcome Measures	VAS-A, VAS-P, expectancy questionnaire, POPM tool
Statistical Analysis	Demographic characteristics were noted using appropriate descriptive statistics for all

	categorical and continuous variables. As both VAS-A and VAS-P were assessed multiple times for the same patients, mean scores of these measures were compared using the repeated measures analysis of variance (ANOVA), including multivariate analysis of variance (MANOVA) tests in the general linear model. Expectancy questionnaire responses were analyzed using a 2-sided, paired t-test. Mean POPM scores were compared using an independent t-test. An alpha of 0.05 was used for all statistical tests, and all analyses were done using SAS® 9.4 (SAS Institute Inc., Cary, NC).
Interim Analysis	N/A
Subgroup Analysis	N/A
Safety	This trial used the U.S. Department of Health and Human Services' Common Terminology Criteria for Adverse Events, Version 4.0 (published May 28, 2009; revised June 14, 2010) for toxicity and adverse event reporting.
Closure	The results will be submitted to medical meetings and peer reviewed journals