Effect of Music on the Reduction of the Sedative Dose During Coronary Angioplasty: A Control-case Comparison Clinical Study

MusicSeda

STATISTICAL ANALYSIS PLAN

Version n°1.0 dated of 15/12/2018

Administrator:

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SIGNATURE OF THE STATISTICAL ANALYSIS PLAN

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Date: *15/12/2018*

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Signature

SOMMAIRE

1. STUDY SYNOPSIS

Music therapy has been validated in the management of chronic pain and anxiety disorders. A program of music therapy will be proposed by the American Hospital of Paris. The objective of this study is to evaluate the effect of the music on the sedative use during coronary angioplasty.

This is a non-blinded, non-randomized controlled pilot study with patients who will be followed during their coronary angiography procedure and with no follow-up.
Patients will be recruited from the coronary angiography patient pool of the American Hospital of Paris and assigned to one of 2 groups in a non-randomized manner. It is expected to enrol around 100 patients, and this is estimated to be obtained in a period of 2 months approximately. Patients will be placed in the control group, without music intervention, or assigned to the music group. Assignment will be done in this manner due to limited availability of the hardware and software to the investigation team. Patients in both groups will be matched based on age, sex, weight, height, American Society of Anesthesiology (ASA) score, and prior medical history, including diabetes, hypertension, chronic kidney disease and stroke. Each patient will receive a standardized sedation, using intravenous sufentanil and midazolam titration to reach Bispectral index (BIS) score below 90 and sedation score ≤ 1.

2. OBJECTIVES

2.1. PRIMARY OBJECTIVE

To evaluate the effect of music therapy on the use of sedative medication during the intervention.

2.2. SECONDARY OBJECTIVES

- To evaluate the effect of music therapy on anxiety and pain scores.
- To evaluate the effect of music therapy on physiological parameters.
- To evaluation patient's satisfaction.

3. EVALUATION CRITERIA

3.1. PRIMARY ENDPOINT

Use of sedative medications.

The studied variable will be the consumptions in intravenous midazolam and/or propofol required to reach sedation score 1 from 4 and/or BIS range of 80-90 during the coronary angioplasty and/or angioplasty.

3.2. SECONDARY ENDPOINTS

- **Pain and anxiety scores.**

Pain and anxiety scores will be measured using the Numeric Rating Scale (NRS), the Visual Analog Scale (VAS) and the Amsterdam Preoperative Anxiety and Information Scale (APAIS) will be completed right after the end of the procedure in the recovery room.

- **Effect on physiological parameters**.

The following physiological parameters will be measured: BIS, heart rate, systolic, diastolic and mean arterial blood pressure, oxygen saturation between 10 minutes prior to the beginning of the procedure until 45 minutes after it.

- **Satisfaction of the patient**

Satisfaction will be measured using a scale from 0 to 5, with a higher score for a high satisfaction.

4. STUDY POPULATION

Intent-to-treat (ITT) Population: all the patients randomized who undergo the coronary angiography procedure.

5. STATISTICAL METHODS

5.1. SAMPLE SIZE CALCULATION

As this is a pilot study, no formal sample size calculation has been performed. However, the number of participants necessary was estimated at 100 in order to get a sufficient power. Since there was no follow-up, increasing the sample size was not necessary to mitigate for missing data.

5.2. STATISTICAL METHODS USED

All the tests will be realized with α =5% using BiostaTGV website.

Baseline characteristics

Baseline characteristics will be summarized. Qualitative variables will be described using number of patients, percentage. Quantitative variables will be described as number of patients, mean, standard deviation, confidence interval of the mean, median, Q1, Q3, minimum and maximum.

Analysis of primary endpoint

Comparison of consumption of medication (dose) will be performed using Student t-test or Wilcoxon rank sum test (non-parametric form of student t-tests, if distribution is not normal). The analysis will be performed in intent-to-treat.

Analysis of secondary endpoints

Secondary endpoints as quantitative variables will be analyzed using Student t-test or Wilcoxon rank sum test (non-parametric form of student t-tests, if distribution is not normal). No statistical test was performed on physiological parameters.