Official Title:

Efficacy of Propofol Combination with either Ketamine, Dexmedetomidine or Midazolam for Sedation during Upper Gastrointestinal Endoscopic Procedures: A Prospective, Randomized, Comparative Study

NCT Number:

Pending (to be assigned by ClinicalTrials.gov)

Document Type:

Statistical analysis plan

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Methodological Approach of a Research Protocol
A Review Checklist

Title of the Research: Efficacy of Propofol Combination with either Ketamine, Dexmedetomidine or Midazolam for Sedation during Upper Gastrointestinal Endoscopic Procedures: A Prospective, Randomized, Comparative Study

Name of Researcher: Hazem Mohamed Sabry Abdelaziz

Specialty: Anesthesia

Type of Research: MD degree

I- Research Objective

a. **Well formulated objective:** √

Proposed reformulated objective: To compare the following sedative combinations (ketamine-propofol, dexmedetomidine-propofol and midazolam-propofol) as regard the recovery time for patients undergoing elective upper gastrointestinal endoscopic procedures.

Objective conforming with study design √

II- Study Design Review

a. **Type of Study Design:** -----

b. **Proposed study design:** Three Arms Randomized Clinical Trial

III- Sample Size:

Using G power software for sample size calculation: setting power at 80% and α error at 5%, it is estimated that a sample size of 66 patients undergoing elective upper gastrointestinal endoscopic procedures (22 patients receiving ketamine-propofol, 22 patients receiving dexmedetomidine-propofol, and 22 patients receiving midazolam-propofol combinations) will be needed to detect a statistically significant difference between the three groups as regards the recovery time in minutes, assuming a large effect size (f=0.40) regarding ***Tekeli et al., 2020,*** using F test (ANOVA: fixed effects, omnibus, one-way).

Assuming that the dropout is of 10%, a sample size of **at least 75 patients undergoing elective upper gastrointestinal endoscopic procedures (25 patients per group)** will be needed.

IV- Missed Items to be added: ----------

C E O M

Name of Reviewer: Dr. Shaimaa Samy Yousef **Date:** 28/2/2024