Medical Biostatistics Unit review report for sample size calculation

Individual details:

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Your status *
-- Please select –
Master postgraduate student ✓
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Research information:

Research title:

Clinical Evaluation of a Modified Technique for Free Gingival Graft Stabilization Using Titanium Fixation Tacs Around Implants Versus Conventional Suturing Technique: A Randomized Controlled Clinical Trial.

Research question:

In patients with inadequate keratinized gingiva undergoing soft tissue augmentation by free gingival graft, will graft stabilization using Titanium fixation tacs affect the amount of keratinized tissue gain compared to graft stabilization using sutures?

Complete items used in sample size calculated * (Basegmez, C. e*t al.,* 2013)

- The outcome used (State 1ry or 2ry): **Primary outcome: width of the keratinized gingiva**
- Values used for outcome (e.g. mean difference, percentage, proportion..... etc): **mean difference and standard deviation**

    - Entry 1: (mean difference between 2 groups, mean and standard deviation of group 1, proportion 1 or estimated prevalence): **mean**: & **standard deviation** according to **(Basegmez, C. e*t al.,* 2013)**

Mean of Group 1 = 3.58

SD of Group 1 = 0.4

    - Entry 2: (standard deviation of control group, mean and standard deviation of group 2, proportion 2 or clinically important difference): **minimal clinical important difference estimated to be 0.5**

- Alpha level of significance: **(5%) (0.05)**
- Effect size used in calculation:
- Power of the study: **(80%) (0.8)**
- Statistical test used: **Independent t-test**
- The calculated sample size**: 11 subjects in each group**
- Increased number for anticipated missing data: **13 subjects in each group to compensate for a drop-out rate of 20%. (total sample size 26).**
- Sample size calculation was performed using PS power

    Upload*
- Applicant's protocol written based on Faculty templates.
- Article used by applicant for sample size calculation.

Decision of MBU:
- Accepted   [x]

- Needs modifications   [ ]

    What to be modified:

- A meeting is needed   [ ]

Date of meeting: /   /   Time of meeting: Place of meeting:

N.B. If you couldn't attend the meeting, show up to apologize or contact your reviewer by e-mail to set up another convenient time.

MBU member: Associate Professor Dr. Weam Elbattawy

MBU Director: Professor Dr. Noha Ghallab

* Date of submission 08 / 09   / 2024   Date of approval: 13 /   10 / 2024
                                                Vice Dean for Postgraduate affairs and research