

Informed Consent Form

1. Investigator: Eugênio César Mendes

2. Name of the Clinical Trial: “COMPOSITION OF GUIDELINES FOR PRE, PER AND POSTOPERATIVE MEASURES FOR PREVENTION OF SURGICAL SITE INFECTION”.

I fully understand that I was invited to participate as a volunteer in this research.

The purpose of this trial is to evaluate the effects of applying antisepsis with degermant chlorhexidine + alcoholic chlorhexidine and antisepsis with degermant chlorhexidine + 70% alcohol + alcoholic chlorhexidine, as well as which bacteria can grow in the proper cultures, and which antibiotics should be efficient in the preoperative prophylaxis of a given patient submitted to surgical procedures performed by the Orthopedic Service of the Samuel Libânio Clinical Hospital, in the city of Pouso Alegre, Minas Gerais. It aims to analyze the efficacy of the antiseptics used in the preoperative preparation procedures of patients, as well as bacterial growth and the due antibiogram, all in order to assess the preoperative prophylactic antibiotic therapy. I was advised that the patients will be divided into two groups of 85 patients each (groups A and B), which sums 170 patients up. Before starting the trial, a table of computer generated random numbers will specify the group in which each patient will be placed. An opaque envelope will be prepared for each patient, it will be sealed and numbered sequentially and will designate the patient's group.

The first group will be submitted to antisepsis with degermant chlorhexidine + alcoholic chlorhexidine.

The second group will be submitted to antisepsis with degermant chlorhexidine + alcohol + alcoholic chlorhexidine.

All members of the trial will be evaluated regarding the effectiveness of the applied antisepsis, as well as which microorganisms may grow in the performed cultures and which antibiotic is the most suitable for the prophylaxis of these bacteria.

The laboratorial evaluations will be carried out by the same biologist at the clinical analyzes laboratory, and all the exams will be documented through an attendance form, which has been developed for this specific trial.

I must decide whether I want to collaborate on this research by understanding it enough in order to come to a conscious decision. If I do not want to participate in this research, I am aware that my medical treatment will be conducted in the same way it would be regardless my participation.

My participation in this trial is unpaid, as well as the researchers will not have any financial benefit from it.

3. Confidentiality: I am aware that my identity will be preserved, and that the information obtained from the research will be disseminated in the scientific community, in such fashion where the results cannot possibly be related to me.

4. Risks: This trial offers minimal risks to the patient's physical and/or mental health, if they occur, they are due to the medications' side effects, which, according to the medical literature, are very rare and, when present, are usually transient.

All the medications used in this trial are already part of the preoperative prophylaxis currently used by the mentioned Hospital and no harm to the patients has been manifested.

5. Right to Refuse or Withdraw:

I understand that my participation is voluntary and that I have the right to refuse or withdraw my consent at any time, without prejudice to my current or any other future treatment in this Institution.

I state and confirm that I have been told and explained in detail about this research objectives, as well as the procedures I will be submitted to. Also, that I have fully read and

understood this consent form. Therefore, I agree to participate in this research and I declare signing two copies of this document, one to myself and the other to the physician in charge, who is also signing both copies.

In case of doubts and if the patient wants to be better informed, he or she can contact the Research Ethics Committee (REC) at the Faculty of Health Sciences "Dr. José Antônio Garcia Coutinho ", which is the department that will supervise this research from the ethical standpoint. REC's hours are from Monday to Friday, from 9:00 am to 12:00 pm, 1:00 pm to 6:00 pm and 7:00 pm to 9:00 pm, its phone number is (35) 3449-9270 and 3449-9271, in Pouso Alegre, MG.

Pouso Alegre, ____/____/____

Patient

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