EFFECTIVENESS OF USING THE GEL OF PAPAIN IN THE WOUND HEALING: CLINICAL TRIAL

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ABSTRACT

Currently considered chronic wounds public health problem due to the large number of events, the high costs of treatment and their impact on the quality of life of the patient. This clinical trial evaluating the effectuation wants the use of papain gel in the healing process of leg, contributing through the evidence found to update the knowledge of nurses and nursing students and providing a basis for decision-making and other research scientific.

Descriptors: Papain, effectuation, nursing.

PROBLEM SITUATION AND ITS SIGNIFICANCE

Leg ulcers are considered a public health issue due to their high incidence, cost and recurrence rates. It is a syndrome that causes destruction of skin structures such as epidermis and dermis, affecting also the deeper tissues. They are normally located in the lower third of the legs. The three main causes of these ulcers: venous, arterial, and neuropathic. A venous ulcer is the most common, representing about 75% of the causes[1]. A product used to treat wounds is papain, which comes from the latex of the papaya tree *Carica papaya*, commonly found in Brazil[2]. It is a chemical debridement whose use in Brazil dates back to 1983 and, after several studies at national and international levels, has been recognized for accelerating wound healing processes, especially chronic ones. Papain can be used at various healing stages, with different concentrations according to the type of the wounded tissue[3]. According to published studies, papain has been used in the form of powder or gel. However, there is a need for

more rigorous research methodology to obtain stronger evidences of the effectiveness of papain[3].

The objectives of this study are: use of papain-based gel in leg ulcers, which may be of venous, diabetic or mixed origin; describe the clinical development of leg ulcers treated with papain-based gel and analyze the effectiveness of it in tissue healing process through the percentage of healed wounds, the rate of reduction in wound areas, mean healing time and tissue changes in the wound bed. As a method, it is a controlled clinical trial. It's also a prospective trial on the use of Papain-based Gel in leg ulcers, with historical control of the patients who used the hydrogel in the same type of injury.

The primary outcomes to be observed in the study are: percentage of healed wounds and rate of wound area reduction; mean healing time; changes in the wound bed tissue. The secondary outcomes to be observed are the lesion exudate, depth, surrounding skin, odor, pain and adverse reactions, using the reporting forms Adverse Drug Reactions, Ministry of Health.

The research will be carried out at the Outpacient Wound Healing Center of the Antônio Pedro University Hospital (HUAP), Universidade Federal Fluminense (UFF), which is situated on the ground floor of the hospital and coordinated by a professor from the School of Nursing and also graduation, residence and post graduation teaching site. The sample comprises all patients, voluntarily willing to participate in the study, who had their leg ulcers treated at the Outpacient Wound Healing Center of Antônio Pedro University Hospital, between April and September 2011. The ulcers have to be greater than two cm^2, with indication of use of papain-based gel. For data collection, descriptive tools will be used to assess the patient's clinical status and injury, already validated by other studies and part of the outpatient service centres' protocols.

Data collection started after the production of papain-based gel by the pharmacy of the Pharmacy School.

Each research subject will be assessed for a period of ninety days, which corresponds to the same period of care service for the control group. Patients will use only the papain-based gel 2% at home and in the clinic once a week if the wound presents granulation. If

the wound presents slough, papain-based gel 4% will be used, but only in the clinic setting. The material for home care treatment is given to the patient or legal guardian, who was trained to change the dressing daily, according to service routine. A folder with the necessary guidance was made available.

The data will be accomplished through probabilistic statistical analysis by intention to treat and will be stored in Excel format and presented in graphs and tables with statistical analysis.

After analyzing the data, the primary and secondary outcomes will be presented, and also the baseline data for each group, with results interpretation, taking into account the original assumptions, bias and chance. The study will be evaluated for its generalization capability and external validity of the findings, and will correlate the results with the current global evidences.

It is worth noting that the present study is part of two major surveys, namely the "Use of Biomaterials in Tissue Healing of Tissue Injuries", developed by the School of Nursing Aurora Afonso Costa; and "Implementation and Evaluation of actions with the aim to Optimize Pharmaceutical Care", both with financial support from FAPERJ, CNPq scholarship support and Science and Technology Incentive Award for the SUS– 2007, on the development of hydrogels.

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Project information: Approved by the Ethics Committee in Research of Faculdade de Medicina, da Universidade Federal Fluminense, register no 196/08 in 07/11/2008. Em processo de registro no "REGISTRO BRASILEIRO DE ENSAIOS CLÍNICOS" com Universal Trial Number (UTN): U1111-1122-9547.

Financial support: FAPERJ. Edital do programa: Apoio a grupos emergentes de pesquisa RJ/2008.

Financial support to Professional Master's degree: Conselho Regional de Enfermagem – RJ.