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Evaluation of life quality in patients with head and neck squamous cells carcinoma before and after the appearance of Oral Mucositis (OM) caused by chemotherapy treatment with Cisplatin associated with Radiotherapy: Relation of the Presence and Level of OM in second phase clinical study comparing the treatment of OM between a phytotherapeutic and application of low intensity laser.

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Abstract

One great challenge of head and neck cancer treatment with Cisplatin and Radiotherapy is the development of adverse side effects that diminishes treatment adhesion, among them is Oral Mucositis (OM). The "golden pattern" nowadays for OM treatment in Brasil is the application of low intensity laser, however this treatment is obsolete, since there are not enough trained professionals in this technique. Previous studies with *Arrabiadaea chica* have proven that the use in healing processes is not only effective, but safe, since no toxic or adverse effects were observed in phase I clinical trials with gel formulations containing 2,5% standardized *A.chica* extract. Therefore, in this second phase clinical trial the comparison of application of 2,5% *A.chica* gel with low intensity laser treatment were evaluated in patients under treatment of head and neck squamous cells carcinoma that developed OM. Once approved, *A. chica* formulation will present a simpler, more effective and low cost option for OM treatment of SUS patients.

Key words:

Arrabiadaea chica, Oral mucositis, low intensity laser.

Introduction

Oral Mucositis is a side effect of some cancer treatments that consists in wounds and ulcerations of the mouth that can inable patients to eat (Sonis, 1998; Sonis et al., 2001). The lesions are very painful and there's only one kind of treatment used in the SUS (Unique Health System): low intensity laser. Although the equipments and maintenance are low cost, the problem in this way of preventing and treating OM stands in the lack of qualified professionals in this technique. Moreover, the Government encourages the research of Brazil's natural resources, being *A.chica* one of the plants included in RENISUS list.¹

Former studies with *A. chica* in mice showed this plant's healing properties that prompted the question: would this plant extract be an option for the treatment of OM in a muco-adhesive gel form? That question motivated the start of phase one and two clinical trials at the Universities hospital facilities.

Results and Discussion

The non-clinical tests began in mice that had OM induced by 5-fluoracil. Once with OM, the animals received *A. chica* crude standardized extract. The results showed that the extract not only had important effects on healing process, but also demonstrated the ability to induce proliferation of fibroblasts and synthesis of collagen in vitro. With that data, phase one studies were initiated.

Phase I study demonstrated that the gel is simple to apply, low cost and does not cause any side effects or toxicity, what thrives the idea that *A. chica* could be an alternative to employ with patients affected by OM.

The studies were conducted with healthy volunteers at CPQBA Unicamp, that had knowledge of the research project and procedures that were being put into, during 30 days. The formulation was dispensed to volunteers once a week, in individual 10g pots with pumps to apply 3 times daily, in 4 different regions of the oral mucosa. The

results found in this phase I study were exactly as expected: with no side effects, toxicity or discomfort in the patients and prompted phase 2 study, already ongoing.

This second phase compares the former accepted treatment (laser) with *A. chica* treatment, separating 2 branches of research: patients receiving head and neck chemio (Cisplatin) and radiotherapy with OM that will be treated with one application of low intensity laser and patients in the same condition that will be treated daily only with the *A. chica* gel in the oral cavity, until the signals/symptoms disappear. The patients with the first signals/symptoms of OM will be split by chance in these two branches, randomly.

They will be evaluated daily by the responsible researcher for local pain and measurement of the lesions in the oral cavity to verify if the gel can be a safe option in OM treatment.

Conclusions

The Project has achieved protocols, scheme of attendance, physical structure and control systems implementation and the authorizations by Ethical Committees. The next steps consists in randomizing the patients at the Clinical Oncology Ambulatory at the University Hospital in two to verify if *chica* gel is a suitable substitute to laser therapy for OM affected patients.

Acknowledgement

¹ Brasil, 2009 Relação Nacional de Plantas Medicinais de interesse ao SUS (Rensisus), acesso em 02 de setembro de 2013 em <http://portal.saude.gov.br/portal/arquivos/pdf/RENISUS.pdf>