Using Gum Arabic for Cancer Patients to Protect From Oral Mucositis Caused by Chemotherapy: An Experimental Study

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Study protocol

Background

Investigate agents which can be used to prevent or treat chemotherapy-induced oral mucositis is a primary concern for clinicians and researchers. The synthesis pharmacological drugs are costly and associated with much side effects resulting in patient non-compliance. So, there is a need to find alternative therapies especially from natural sources as these are cost effective and have no or minimal side effects. In this regard, Gum Arabic is very convenient since this polymer is readily available on nature and does not require any further complex method of purification. Also it is a safe material for biological applications.

Objective of study

The purpose of this research was to investigate the effect of Gum Arabic to prevent chemotherapy-induced oral mucositis in cancer patients.

Inclusion criteria

Patients whom well diagnosed with cancer in any stage were eligible for enrolment if chemotherapy is a part of the treatment plan.

Exclusion criteria

Patients will be excluded if recently received chemotherapy or radiotherapy, presence of oral mucositis or periodontitis, or there is evidence of any systemic diseases.

Dose, preparation and administration of gum arabic

The daily dose of Gum Arabic will be divided in 30 grams sachet, the content of sachet will dissolve once in 100 ml purified water to form solution, and consuming

in six divided doses. Patient will provide by measuring cap to using 20-ml every two hours as mouthwash for a minute then swallow.

The total number of sachets are 42 for a period of six weeks; each patient will give 21 sachet of Gum Arabic at the first day of chemotherapy treatment to be used during the next three weeks of the treatment period, then the remain quantity (21 sachets) will provide for the next three weeks.

Modification on the preparation and administration

Because frequent use during the day (six times; each 2 hours) and high viscosity of gum arabic solution, which lead to withdrawn some patients after were enrolled in this study. Researcher was tried to solve this problem at two sides; firstly, by increasing the quantity of purified water as solvent for Gum Arabic to 250 milliliters instead of 100 milliliters to reduce viscosity of solution. On the other hand, patient was informed to use this quantity of solution twice daily; half at 9 morning and the remaining half at 9 evening to decrease frequent uses.

Oral mucositis assessment:

Based on a combination of subjective, objective and functional outcomes, using World Health Organization Oral Toxicity Scale (WHO Score): subjective – soreness as described by the patient, objective – presence of erythema and ulcerations, and functional – ability to eat solids, liquids or nothing by mouth

Assessment gum Arabic effect

For each participant data of oral mucositis will be start after getting ethical committee permission & permission from Radiation and Isotopes Center of Khartoum (RICK) authority. Informed consent also will be taken from study participants.

Data will gather via data collection sheet which composed of two sections; that will fill through six weeks of patient follow up. The first part for assessment patient regarding oral mucositis after chemotherapy by weekly telephone call for patient based on ready-scheduled appointments. The second part contain a basic information and characteristics of patient, which will record by researcher during the first day at first cycle of chemotherapy. In addition, there is meeting with patients by researcher in chemotherapy rooms when the participant return to the next cycle of chemotherapy either weekly, bi-weekly or every three weeks, according to treatment regimen.

When the researcher is contacted with the patient either by telephone call or when meeting participant in the hospital during the next chemotherapy cycle; there will be specific questions directed by the researcher to be answered by the patient regarding oral mucositis. Those questions will be summarized as follow: 1. Does the oral mucositis was occurred during this week? 2. If Yes. Is there was soreness, erythema, ulcers in mouth of participant? 3. The day that oral mucositis was started and eliminated? 4. If the patient belong to study group; Is Gum Arabic still used regularly? Six weeks for each participant from starting therapy.

Cessation of trial therapy

No stop for recruiting the participants to study group until the planned number was completed, but there was a period of three weeks the new recruitment was suspended to separate study group from control group in try to reduce the bias (reduce the confounding) between the two groups and give a chance to follow up the study group patients. By August 2016 we stopped participants recruitment and follow up; since the sample size proposed and follow up planned was completed.

Statistical analysis

The collected data were arranged, coded, tabulated, and introduced to a personal computer using Statistical Package for Social Science (IBM SPSS Statistics 20.lnk). P. values equal or less than 0.05 was considered significant. The data of 332 patients who completed this study were documented and reviewed to give a qualitative analysis of the frequencies. The descriptions were based on the data that documented from personal file of patient in designed sheet prepared by the researcher. Data were presented and suitable analysis was done according to the type of data obtained for each parameter. All numeric variables were expressed at 95% confidence intervals. Student t-test was used to assess the statistical significance of the difference between means of the two groups.