

Title of Proposal:

Eradication of Malignant Melanoma While Preserving Healthy Surrounding Cells

Methods and Materials

Study design:

I will set up a study involving malignant melanoma patients. Because I will be dealing with humans, I will seek approval from IRB, the institutional review board, at Florida Gulf Coast University.

The patients in the study will be selected based on their gender, age, and skin composition in order to better replicate a broad population. There will be three groups. Group one will be treated with the intratumoral vaccine injections. Each patient in group one will be injected directly into the tumor with α -gal glycolipids micelles suspension that will trigger a cascade of events in the patients' immune system to target the mutant cell for destruction and also to create future immunity against mutant cells.[6] Group two will orally receive the drug Tykerb. This is a chemotherapeutic drug that is specific enough to infiltrate the mutant cells and inhibit ERBB4, a gene involved in the growth of melanoma cells.[7] Group three will receive both the vaccine and the oral treatment. The goal in combining the two treatments will be to observe whether it will prove beneficial in the remission of melanoma. The progress of the treatment will be assessed by a group of doctors monitoring the participants, records will be kept and further analyzed to determine a successful and less invasive method.

Data Collection:

I will carefully and thoroughly record the progress of the treatment of each group in a clinical setting by: Analyzing the affected areas (the lesions) and surrounding cells (skin immediately surrounding the tumor). I will be tracking the size reduction and/or disappearance of the tumors by measuring them. We will perform a complete health evaluation, as well as overall wellbeing, of our patients at the beginning of the study and on a weekly basis, for the first six months, and monthly for the remainder of the year period.

The results of the progress made by groups one and two our two will be compared to the results of the progress made by group three. Data will be analyzed collecting and charting the progress of the applied treatments. The lesion size will be indicative of a reduction or disappearance. Surrounding cell damage will indicate if the treatment was non invasive to the healthy cells immediately surrounding the tumor. The overall wellbeing of the patient will help me assess if the treatment is beneficial or detrimental to their overall health.

Data Analyses:

The collected data from each group will be compared using ANOVA, because I will have three groups to compare. I will reject a p-value higher than 0.05. I feel because we are dealing with humans we must hold accuracy valuable. Graphs and charts will be constructed to better understand my results and determine the effectiveness of combining the intratumoral vaccine injection with the orally administered drug, Tykerb.

Title of Proposal:

Human T-cells response to influenza H1N1 vaccination: a comparison between youths and senior adults

MATERIALS AND METHODS:**Experimental protocol**

First, IRB permission will be obtained. Eighty healthy seniors (over 65) and eighty healthy youth (9-16) will be selected to participate in this experiment. All subjects should have clear history of no chronic diseases and in healthy conditions. All participants will be informed and consent to this study. They will be vaccinated with the H1N1 influenza vaccine. Their venous blood samples will be collected at three different times: before vaccination and at four and twelve weeks after vaccination. After each of these collections, their blood samples will be used as below.

In laboratory

Peripheral blood mononuclear cells (PBMC) will be cultured and prepared as following: PBMC will be extracted from participants' venous blood samples by banding in Ficoll-Paque, sterile medium to isolate human lymphocytes and resuspended in AIM V media⁷. These cells will be cultured and stimulated with live H1N1 viruses⁷. Since, the peak productions of these proteins have been previous detected at the second day for IL-2 and after six days for IFN- γ , IL-10 and granzyme B, so their assays will be performed at these time points⁷. PBMC lysates and their supernatants will also be stored at low temperature. Cytokine and granzyme B activities will be analyzed as below.

Assay for IL-2 activity

IL-2 activity will be determined by assaying the supernatants. RPMI media which contains 1 mM of 2-mercaptoethanol and 10% of fetal bovine serum, the medium to support growth of culture cells, will be used⁸. IL-2 proliferation will be measured by [³H] thymidine incorporation assay⁹. Through this measurement, the minimum level of detection (MLD) will be presented as U/ml⁹.

Assays for IL-4, IL-10 and IFN- γ activity

IL-4, IL-10 and IFN- γ assays will be performed on day sixth. ELISA, enzyme-linked immunosorbant assay will be used to detect the presence of these interleukin and interferon in PBMC supernatants⁹. The MLD for each interleukin and interferon assays will be determined in pg/ml or U/ml⁹.

Data analysis

All data will be expressed as mean \pm S.E.M (standard of error of the mean) and will be graphed to compare between two age groups at three different time points: prevaccination, 4-weeks post-vaccination, and 12-weeks post-vaccination. The data will be analyzed by analysis of variance (ANOVA) and the statistical significant will be established for p-values of smaller or equal to .05. The T-cell responses and vaccine efficiency will be determined through the comparison of cytokine activities for significant changes pre-vaccination versus post-vaccination. Comparing between 2 age groups will be used to determine the age-related changes in the immune system.

Title of Proposal:

‘How Does Raw Food Diets Affect Body Weight and Menstruation in Young Women?’

Methods:

Study Design:

Observation of Weight-Loss:

First, I will need to solicit volunteers for my study from college-aged females at Florida Gulf Coast University, Edison College, and Hodge’s University. Because I need a control group, I will also need to advertise to young women currently not on a raw-food diet but who are willing to try it. I will need three groups of women: One group that eats exclusively raw-foods (at least 90% raw-foods in their daily diet), one group that eats moderate amounts of raw-foods (At least 60% raw-foods in their diets), and one group (my control group) that are not currently on any form of raw-food diet and eats mostly cooked foods. I would like to obtain at least 20 women for each group so that I will have a large enough study to encompass my whole question and sufficient data for each part of that question. To answer my whether raw-food diets affect body weight, I will have to determine the weight of each of my participant. Then I will use a tape measure to determine each woman’s height and their chest, waist, hip and thigh ratios.⁹ I will use a correlation coefficient formula to gauge how strong the correlation is between their weight and menstruation values. I will do the same procedure for each individual in each group and then collect my data on a chart monthly.

Data Collection for Menses Observation:

Studies have also shown that adhering to a raw-food diet long-term can cause the absence of a monthly period (amnorhea) in young women.³ In order to demonstrate the causality between maintaining a raw-food diet and the absence of a monthly period, I will compile data concerning the women’s menses over a six-month period.

This portion of my experiment will run concurrently with the experiment of body weight. During the first month of my study (the same month that I weigh the participants) I will pass out a questionnaire to all of the women in all three of my groups.³ Because this part of my study is so intimate, I plan to pay my subjects a flat fee for participating until the conclusion of the study. The questionnaire will ask a multitude of questions (for example: “How long is your menses?” and “Describe the color of your menses” and provide a color chart) detailing the amount, duration, color, and quality (thin or thickness) of their menses.¹⁰ After filling the questionnaire out and at the completion of their menses, I expect to obtain the participants complete questionnaire. At the conclusion of my study, I will then compare the monthly sets of data (the data that shows the affect of raw food diets on weight loss and the data that exhibits the changes in menstruation), combine them to obtain correlation, and formulate the answer to my question.

Data Analysis:

In order to analyze my data, I will run an analysis of variance or ANOVA test to statistically analyze my results. I will choose to apply an ANOVA test because I have three groups and I need my observed variance to be partitioned into separate independent variables (one for body weight and one for menstruation) so that I can draw a correlation between the two variables. I will then plot them on a contingency table so that I can observe the strength of the variables correlation in a range from 0 to 1.

Title of Proposal:

How does the importance of diet and oral hygiene education in children affect their oral health throughout their life?

Methods

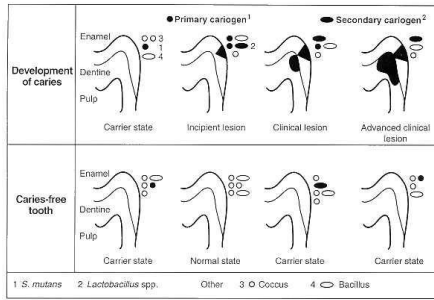
Study Design:

For the design of this study I plan to obtain a sample of fifty children, ranging in two to twelve years of age, from one of the local area schools that can accommodate these parameters. I plan to obtain the sample of children from an after school program that has been previously set up by the designated school. (Note: Children should have parents with them for this experiment, due to the fact that any diet or oral hygiene habits are being dictated by their decisions.) In this observational/experimental study I will take the sample of fifty children and divide them evenly into two groups: Educated vs. Non-Educated Control. The educated group will take a two week a diet and oral hygiene course after school for about an hour each day, and the non-educated control will consist of children that do not take part in the two-week course.

The education class will be based on how to brush and floss your teeth properly, and what you should eat to be a healthy child. There will be guided meal plans and daily oral hygiene routines provided to the children of the educated group, while the non-educated control will not change their daily routines at all. After the education course has finished, I then plan to wait for a month to start making observations on the condition of the teeth for the two groups. I will compare from the initial condition of their teeth before the course by having them each go through an oral examination by a local dentist and then how the groups differ from just a month later. From here on, every two weeks for a total of five months comparisons will be collected on dental caries development, plaque buildup, and tooth strength.

Data Collection:

The process of data collection will first consist of questionnaires about what their normal diet and oral habits are before and after the education course that will be answered by the parents and the children. Then I will have a licensed dentist come to evaluate the teeth for children who have developed dental caries and those who are caries-free; data for both groups will be taken into account³. Throughout my education course I plan to also develop strategies on how to educate parents and children on how to develop their oral health patterns⁵. If there is a healthy routine that is used in the parents daily life, then most of the time this will be passed on to the children. To quantify caries development, plaque buildup, and tooth strength I will be using a Decayed Missed Filled Teeth Index². The DMFT calculates each decayed tooth, missing tooth, and the teeth that have fillings in order to have a score that ranks how poor or good the teeth are. In addition to the DMFT, I will also be using data from the third National Health and Nutrition Examination Survey to see how dietary habits and dental caries correlate⁴. The basis for this experiment is not only to see how oral hygiene habits are affect dental caries, but also the effects of a healthy diet in a child's primary teeth will be a key component to collecting and analyzing the data. The final component that will aid my experiment in collecting data is the idea to use data from other experiments to try and merge concepts in order to aid in various ways for diagnosis and treatment of dental caries for primary teeth⁷. Being able to decipher the decay on each tooth and how it was developed is only half the battle, and then you must treat the imperfection. Treatment and prevention is going to help determine how children can have great primary teeth and how they can keep up with good oral habits throughout their life.



http://gsbs.utmb.edu/microbook/images/fig99_2.JPG

Figure 1- The above chart shows the stages of how a normal tooth develops caries from different bacteria such as: *S. mutans*, *Lactobacillus*, Coccus, and Bacillus, which can demonstrate how the DMFT index can be numerically displayed.

Data Analysis:

The DMFT index score will be done with the total sum of each group being counted on each aspect of the index (decayed, missing, filled) and the way I will be analyzing my data is by constructing a t-test. There will be a p-value significance of 0.05 ($p < 0.05$) to decipher whether or not there is a significant numerical change between the two studies. Using this p-value significance I will be able to determine whether the results observed were random, and if the results are proven not to be random I will be able to reject the null hypothesis.