A Placebo-Controlled Double-Blind Study to Demonstrate the Therapeutic Value of Intravenous Vitamin C in the Treatment of Cancer

Cancer & Vitamin C

A large number of studies have been done that document the effectiveness of vitamin C as both a preventive agent and as a therapeutic for cancer. This includes many human and animal studies as well as hundreds of clinical case studies.

Gary Null has produced a review of many of these studies, ***Vitamin C & Treatment of Cancer: Abstracts and Commentary from the Scientific Literature***. This review is available on the Internet at http://www.garynull.com/documents/vitaminc-cancer.htm**.** Dr. Null's preface states "…[W]hat follows is not anecdotal evidence; it is scientific evidence. We can now move beyond the stage of allowing quackbusters, apologists for special interest groups, and other adherents of the flat-earth school of intellectual inquiry to maintain that there's no evidence of the disease-fighting value of nutrients. Because, quite simply, there is, and here it is."

While the results of most of these studies show benefit, sometimes amazingly, they fall short of documenting the true potential of vitamin C therapy because the doses utilized are generally extremely low and never as high as some, including the authors of this proposal, believe is necessary for maximum benefit. Additionally, we are unaware of any controlled trial of the use of intravenous vitamin C.

Controlled Trials – The Difficulties

The medical profession looks to controlled trials, especially double-blind, placebo-controlled studies, as the only truly legitimate method of screening out extraneous circumstances so that the effects of the substance being tested is all that is left. The cost problems aside, there are several reasons that make this type of trial difficult, if not impossible in certain circumstances. The difficulties for vitamin C treatment includes:

Unethical Exclusion of Patients

Cameron and Pauling did the most famous cancer and vitamin C trial at Vale of Leven Hospital. They used hospital records to produce historical "controls" because, as they explained, it would be unethical to withhold this safe, promising treatment to patients that had exhausted all other modalities.

Dosing Problems

For maximum effectiveness oral vitamin C must be given to the patient in the highest dose tolerable. This is the dose just short of the amount that causes diarrhea (known as "bowel tolerance limit"). Multiple daily doses are also required. This level is impossible to gauge for those patients receiving placebo since the dose must be pushed to cause gastrointestinal distress and then backed off. This dosing problem is one reason previous studies have been forced to use smaller, uniform doses for all patients that cannot approach bowel tolerance limit and, therefore, cannot approach maximum benefit either.

Compliance

Patient compliance to the protocol is always difficult. When doses are more than a pill or two a day, as is necessary for vitamin C, this difficulty is multiplied. The opposite side of compliance can also be a problem when the patients know what the substance being tested is and that this substance is safe and readily available at the grocery store. If the substance is possibly effective, why chance being in the control group and receiving no benefit when there is no downside to "supplementing" the protocol on your own?

Our Approach to a Controlled Trial

Our goal is to provide evidence of vitamin C's value, both orally and intravenously, for the treatment of cancer. We would like to produce results that will be convincing to the scientific community and to the general public. For the general public we plan to create a video history of each patient through the treatment regimen. While post-treatment interviews are often used to add a human side to case studies we believe following patients through the therapy, creating a "before and after" story, will be very powerful.

For the scientific community we need documented results from a well-designed and –controlled study.

Making allowances for the difficulties described above, the study protocol would be as follows:

- All patients will receive oral supplements generally following Dr. Abram Hoffer's protocol which relies heavily on vitamin C. Dosage of vitamin C could be fixed at 10-20 grams per day or, given patient cooperation, be based on "bowel tolerance limit"
- Intravenous vitamin C will be given to half the patients in a double-blind placebo situation 3-5 times a week at 100 grams per session.

While this approach is somewhat unorthodox we believe it has merit as it will:

- Allow ALL patients to derive benefit from a safe treatment modality.
- Overcome the compliance and dosage difficulties of a supplement-based controlled trial by having ALL patients participate in the oral portion of the protocol.
- Allow for a placebo-controlled portion that will demonstrate the additional value of the very large intravenous doses with no opportunity for patient "cheating."