

Glutathione: Information for Patients and Families

Results from a small-scale clinical trial using an inhaled form of glutathione have recently been the focus of media attention. Valerie Hudson, Ph.D. — a professor of political science and mother of three children with cystic fibrosis (CF) — and Clark Bishop, M.D. — a pulmonologist — collaborated on the trial that took place in Utah. **Much more work needs to be done to determine the dosage, safety, and effectiveness of glutathione before it can be recommended as a treatment for people with CF.**

What is glutathione?

Glutathione is a naturally occurring antioxidant found in the human body. It is required to maintain normal function of the immune system and plays a protective role against the damaging effects of bacteria, viruses, and pollutants. Scientific evidence suggests that people with CF may have low levels of glutathione in their lungs. Therefore, increasing glutathione levels through oral supplements or via inhalation *could become* a potential therapy for CF.

Can glutathione benefit me or my child?

It is not yet known whether glutathione is beneficial for people with CF or if it is safe as an inhaled therapy. Until the dosage, safety, and possible benefits have been addressed in a large-scale clinical trial, it is not recommended that people with CF use glutathione as a therapy. In the meantime, the CF Foundation recommends that patients continue with their existing therapies as prescribed by their CF physician. **Introducing any experimental therapy — including glutathione — that has not been appropriately studied, analyzed, and approved by the Food and Drug Administration (FDA) for use in patients could have unknown and dangerous side effects.** Any changes in a therapeutic regimen should be discussed with the CF care center physician responsible for the patient's care.

What is the CF Foundation doing to support the development of glutathione?

Over the past three years, the CF Foundation has funded both laboratory and clinical research studies on glutathione and other such antioxidants for their practical application to CF. In fact, much of this work has resulted in the understanding of the scientific rationale for glutathione therapy for CF patients.

In the summer of 2002, in an effort to assist Hudson and Bishop with their planned clinical trial, the CF Foundation asked Frank Accurso, M.D., the chairman of its Clinical Research Committee, to travel to Utah to advise them. An expedited peer-review of the protocol was offered with the intent of funding a study that would be able to answer the question: “is glutathione safe and effective?”

After the review of the clinical trial protocol, leading CF clinical investigators made three recommendations. These included documenting the purity of glutathione, obtaining FDA approval of the trial, and enrolling a large number of patients. To date, the CF Foundation

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National Office

6931 Arlington Road Bethesda, Maryland 20814
(301) 951-4422 (800) FIGHT CF Fax: (301) 951-4422 Internet: www.cff.org E-mail: info@cff.org

has not received a revised application addressing these recommendations. The study proceeded and enrolled 19 patients with CF.

Will the CF Foundation fund a large-scale clinical trial of inhaled glutathione in people with CF?

The CF Foundation is convening a workshop later this year on antioxidants for expert CF researchers and clinicians who will be invited to present and analyze data. This workshop will provide a forum for the experts to reach a consensus on how best to proceed with the study of antioxidant therapies for CF. Glutathione is one of several potential antioxidant therapies that will be discussed.

In parallel, the CF Foundation is working with European investigators who have completed an early-stage, inhaled glutathione clinical trial in people with CF to determine the correct dose and frequency of administration. A larger trial conducted in Europe to test safety and efficacy could start more quickly than one in the United States.

What are the side effects of taking glutathione?

Anecdotal reports of the side effects of glutathione include: bronchial constriction, coughing, headache, feeling of congestion, abdominal discomfort, shakiness, flu-like feelings, nausea, diarrhea, and dizziness.

Who manufactures glutathione?

Glutathione, in pill form, is available from a variety of nutritional supplement manufacturers. It comes in varying concentrations, strengths and formulations and is not regulated by the FDA. Therefore, the amount of glutathione contained in these supplements is not standardized and could be unsafe if taken inappropriately. Glutathione, in an inhaled form, is not available for purchase.

What other potential therapies does the CF Foundation have in the pipeline to treat or cure CF?

The CF Foundation has about two dozen potential therapies in various stages of pre-clinical development and clinical trials — more therapies than at any other time in CF history. Any of these potential treatments, if successful, could make a dramatic difference in the lives of people with CF. Some therapies treat the symptoms of CF, while others address the basic defect in CF cells. A list of CF Foundation-supported clinical trials and their descriptions is available on the CF Foundation's Web site at www.cff.org. The CF Foundation will continue to move these potential treatments forward while also adding new therapies to the development pipeline.

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