

Hypertonic Saline Therapy for Cystic Fibrosis: Is It Right for You?

The Cystic Fibrosis Foundation funded a study in Australia to find out if inhaling a mist of hypertonic saline twice a day would help people with cystic fibrosis (CF). Hypertonic saline is extra-salty water that is sterile, so there are no germs in it. Because CF airways are known to lack enough salt and water, researchers thought a hypertonic saline mist would help clear the thick mucus from the lungs.

The results of this study were first presented at the 2004 North American Cystic Fibrosis Conference and now have been published in the *New England Journal of Medicine* with another article on the same topic from the University of North Carolina at Chapel Hill. This fact sheet will help you learn about this the Australian study. Please talk with your CF care center team to see if a hypertonic saline treatment should be added to your or your child's routine CF care.

How was the trial designed?

People in the study were put into one of two groups. One group inhaled normal saline that was a 0.9% salt solution. The other group inhaled hypertonic saline that was a 7% salt solution. Both groups inhaled a bronchodilator drug (to open airways) then inhaled a sterile salt-water mist using a nebulizer twice a day for a year. During the study, the patients and investigators did not know who was inhaling normal saline and who was inhaling hypertonic saline. Patients were watched closely for any health benefits or any problems while inhaling either solution.

What were the results of the trial?

Both groups had better lung function during the study. However, those taking hypertonic saline had even better lung function than the people taking normal saline. Also, it was found that the people in the hypertonic saline group had fewer lung infections than the other group.

Were there any side effects?

The side effects that were noted by some people included coughing more, sore throat and chest tightness. (It is known that hypertonic saline can irritate the airways.) Your CF care center team may want you to take your first dose of hypertonic saline while at the care center. This is to ensure your or your child's lungs will not have problems from hypertonic saline.

Is hypertonic saline right for me or my child?

Your CF care team can help answer this question. Knowing who was chosen for the clinical trial might help you decide if hypertonic saline is right for you or your child. The people with CF in the study were 6 years old and older and had mild-to-moderate lung disease. People with *Burkholderia cepacia* lung infection were not included in the study. Your CF care team can provide you with more information and may do some tests (sputum cultures) to see if hypertonic saline is right for you or your child.

Who should take hypertonic saline?

We do not know if hypertonic saline is safe for everyone. We do know that people who are 6 years of age and older, or who have an FEV₁ greater than or equal to 40% predicted might be able to take hypertonic saline. Before it can be prescribed, your CF care team will assess you or your child.

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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

Can I make my own hypertonic saline to inhale?

To help prevent any germs from getting into your or your child's lungs, and to make sure the solution contains the right amount of salt, we it is strongly recommended that you only use hypertonic saline prepared by from a pharmacy. Ask your CF care center team which pharmacy in your area can fill a prescription for inhaled hypertonic saline.

The CF Services Pharmacy, a national mail order pharmacy, also can supply hypertonic saline with a doctor's prescription. Also, do not forget to clean and disinfect your nebulizer. If you have questions about nebulizer care, ask your CF care team or read "Respiratory: Stopping the Spread of Germs," available on the CF Foundation's Web site at www.cff.org.

How much hypertonic saline will be taken?

In the study, 4 mL of hypertonic saline was inhaled twice a day. A Pari PARI LC Plus[®] jet nebulizer and a PariPARI Proneb[®] Turbo compressor were used to inhale hypertonic saline during the study. Your CF doctor will prescribe how much and how often you should take hypertonic saline. Ask your CF care team whether you can use your nebulizer and compressor.

If hypertonic saline is added to my or my child's CF care, should other drugs be stopped?

Hypertonic saline is one more helpful "tool" in CF care. It may be used as a part of your or your child's regular CF treatment. It is not meant to replace other proven treatments. **Do not stop any therapy before you talk with your CF care team.** It is always a good idea to talk about all of your therapies with your CF care team to make sure that you or your child are always getting the proper treatment.

Can I save time and mix my other inhaled medications with hypertonic saline?

You should not mix any other medications with hypertonic saline. Unless your CF doctor or therapist tells you to do it, do not put two medications into your nebulizer at the same time.

What is in the future for hypertonic saline and CF?

We need to improve our understanding of how hypertonic saline is to be used. For example, we need to know if a different nebulizer would work better. Also, we need to find out if people who are sicker or younger than 6 years of age will benefit by taking hypertonic saline.

What other drugs are being developed by the CF Foundation?

To find a cure for this disease, the CF Foundation is pursuing several different strategies. It has committed close to \$131 million in science that uses the latest technology to discover new CF-specific drugs. At the same time, the CF Foundation is working to identify "low-hanging fruit," such as hypertonic saline, which are therapies already on the market for other diseases that may have a benefit for people with CF.

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The mission of the Cystic Fibrosis Foundation—a donor-supported nonprofit organization—is to assure the development of the means to cure and control cystic fibrosis and to improve the quality of life for those with the disease. For information call **(800) FIGHT CF** or visit www.cff.org.

Patient participation in clinical trials is essential in the process of developing new drugs and making them available sooner for everyone with CF.