



A NEWSLETTER FOR THE HALT- C TRIAL

HALT-C NEWS

Hepatitis C Antiviral Long-term Treatment against Cirrhosis

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WHAT ABOUT PAIN-RELIEVERS? CAN I TAKE TYLENOL?

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One of the most frequent questions I am asked is what over-the-counter (OTC) pain relievers patients with hepatitis C should take. You have probably heard about liver damage caused by the more than 200 different acetaminophen-containing compounds on the market. This includes Tylenol®, most cold formulas, or the narcotic-containing Vicodin® or Percocet®. Acetaminophen is a dose-related toxin so it cannot hurt you *unless* you take too much! The package labeling of most acetaminophen compounds suggests a maximum daily dose of 4 grams/24 hours (8 extra strength or 12 regular strength pills). Those who sustain severe liver damage have generally consumed at least 6 grams (12 extra strength (500 mg) tablets) in a 24-hour period often for several days in a row or even much larger quantities without any awareness that they could be causing themselves harm.

How does this happen? Many people fail to keep track of how many pills they have taken, or take different preparations without realizing that they both contain acetaminophen. Others simply stop caring and take too many pills out of pure frustration with poor pain relief. Co-factors which may increase the possibility of damage to the liver include drinking (but you

don't do that, do you?), and starvation or missing meals. Only rarely does any liver damage result from taking less than 8 tablets per day. Therefore, it is perfectly safe to take up to 4 and possibly even 6 extra strength tablets per day. Since acetaminophen is not a great pain reliever, it is unlikely that taking more will actually give you more relief!

What about non-steroidals (NSAIDs) such as aspirin, ibuprofen, naprosyn? These medications have very little liver toxicity unless huge amounts are taken. Non-steroidals are harder on the stomach, causing ulcers and dyspepsia but not hepatitis. It is still advisable to limit the numbers of NSAIDs per day to about 4-6 of any kind. Here are four good rules to keep you out of trouble:

- 1) Always read the package labels. Make sure you are not taking two acetaminophen compounds at once. Remember, cough and cold meds usually contain acetaminophen.
- 2) Don't exceed the 4 gram/24 hour limit for acetaminophen under any circumstance. Better still, stay below it.
- 3) Narcotic-acetaminophen compounds are very addicting and can lead to too much narcotic *and* too much acetaminophen.
- 4) If you have bad pain, see your doctor, don't just chew the OTC's!

ISSUES OF INTEREST

Current topics from experts in the field

WHAT ARE THEY DOING WITH ALL MY BLOOD AND LIVER TISSUE? A LOOK AT ANCILLARY STUDIES

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The HALT-C Study's main aim is to determine whether long-term maintenance interferon therapy has any value in slowing the process of developing cirrhosis or reaching the stage of complications; but there are a number of ancillary studies being performed as well. It isn't often that such a large, well-characterized group of patients is available. As long as we have so much valuable information, we are trying to use it in the best way possible to advance our understanding of hepatitis C in general, beyond determining the value of maintenance interferon. You have been asked to answer many questionnaires, give extra blood samples, and generally be a good sport with these added studies. *We appreciate your help!* There will definitely be some great advances from the studies we have underway.

As an example, four sites are participating in the Immunology/Virology Ancillary Study, in which a number of approaches are used to tease out more information concerning the way the hepatitis C virus and your body interacts. We know that your immune response to the virus determines whether you can clear the virus permanently. A small number of people are able to do this when first exposed, but the majority of patients become chronically infected. Some respond to interferon with clearance of the virus, and this depends not only on the drug being delivered, but also on the characteristics of your specific virus and your own response to it. Your own immune system must help out. These studies are directed at determining your immune responses and, at the same time, changes in the virus itself during interferon therapy. Here are the components of the Immunology/Virology Study:

- 1) Tiny parts of liver biopsies are sent to Massachusetts for lymphocyte (white blood cell) studies. Lymphocytes are extracted from liver biopsies to actually determine what parts of the virus the local immune attack cells are directed to.
- 2) Blood lymphocytes are being immortalized (made to last for a long time) for later studies, also in Massachusetts.
- 3) Another tiny portion of the biopsy is sent to Seattle where the frozen tissue is scanned to determine the location of hepatitis C virus inside the liver cells. This is done under the microscope by tagging the virus with antibodies bound to gold particles.
- 4) Two different studies also done in Seattle, using blood samples from which the virus RNA is extracted, are determining the actual sequence of the virus. This technique will help us to determine what is unique about your virus and whether there are any differences between it and other non-responders.
- 5) A series of antibodies are screened in Illinois for special antibodies that might provide a hint at what role this part of the immune system plays in controlling the infection.

All these studies will be coordinated at the end to get maximum mileage and will be reviewed for relevance to what previous treatment you may have had, what stage your disease is in, and anything that will help us study the strange traits of this virus that seems to be able to persist for so long in so many people. Your participation in these studies is vital and greatly appreciated. This is more than just a treatment trial. Remember too, that in all that we do your identity is protected with many guards against breaks in confidentiality. Ask your site investigator if you have questions about any aspect of this discussion. Thanks again for participating!

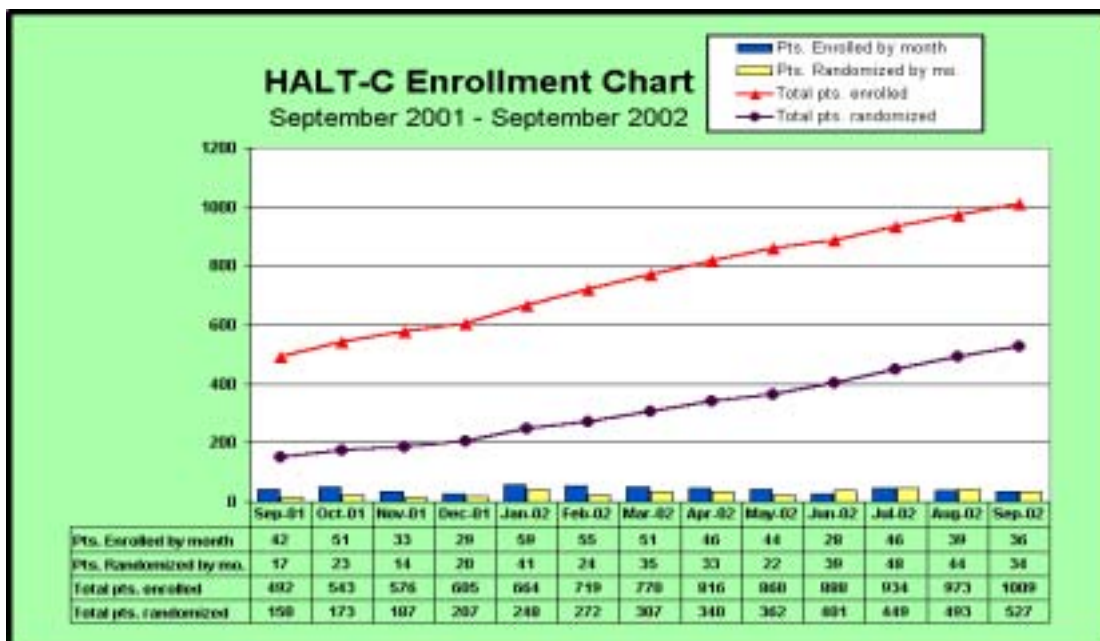


MORE TIPS FOR MANAGING SIDE EFFECTS

From the Coordinators at Saint Louis University

Below is a partial list of possible side effects of your therapy. Our patients have found the following suggestions to be helpful. Many thanks to Rhonda Hageman, NPC, for her input.

- 1) Insomnia (trouble sleeping)
 - a) Take your second daily dose of Ribavirin at 3-4 p.m. instead of taking it at bedtime.
 - b) Learn relaxation techniques.
 - c) Try not to sleep too many hours during the day so that you can sleep at night.
 - d) Get daily exercise. Be sure your exercise is completed at least 3 hours before bedtime.
- 2) Nausea, vomiting and diarrhea
 - a) Drink plenty of water and clear juices (without caffeine or alcohol).
 - b) Taking your Ribavirin with food may reduce nausea.
 - c) Combat nausea by using relaxation methods such as yoga or meditation.
 - d) For occasional diarrhea, switch to bland foods such as bananas, rice, applesauce, and dry toast or crackers until diarrhea resolves. Then advance your diet to regular foods slowly.
 - e) Take over-the-counter medications for nausea and diarrhea. If these do not help, call the office.
 - f) If you have occasional vomiting, sip on clear fluids or ice chips. Then add soft foods such as Jell-O or soups.
 - g) Any vomiting that lasts more than 3 days should be reported to your nurse, nurse practitioner, physician assistant, or doctor.
- 3) Mild hair thinning
 - a) Style your hair in a fashion to make it look fuller.
 - b) Shorter hairstyles may reduce hair loss.
 - c) Use scarves, wear hats, or hair extensions.
- d) Pulling hair tightly into a ponytail can cause increased hair loss.
- e) Avoid using blow dryers and chemical treatments on your hair.
- f) Don't wash your hair excessively. If you wash your hair daily, try switching to every other day.
- 4) Dry, itchy skin and mild skin rashes
 - a) Take short warm (not hot) baths or showers.
 - b) Rotate injection sites.
 - c) Use unscented skin lotions. Eucerin, Curel, and Lac-Hydrin creams are especially helpful for very dry skin.
 - d) Sarna lotion (over-the-counter) is helpful for dry skin and itching.
 - e) Be sure to use sunscreen, at least SPF 15, when going outside. Interferon can make your skin more susceptible to sunburn.
 - f) Try oatmeal baths. Pour one (1) cup of oatmeal into a nylon stocking. Make a knot in the open end of the stocking and drop into a tub of warm water.
 - g) Try over-the-counter hydrocortisone creams or Benadryl spray. Apply according to package instructions.
 - h) Take over-the-counter diphenhydramine (Benadryl or generic) 25 mg, one or two capsules every 4-6 hours as needed.
 1. Call the office before using this product if you have asthma, glaucoma, stomach ulcers or an over-active thyroid.
 2. This product may make you sleepy. Take your first dose at bedtime or on a day when you don't work to see if it makes you drowsy.
 - i) If itching persists, call the office for further advice and/or prescription medications.



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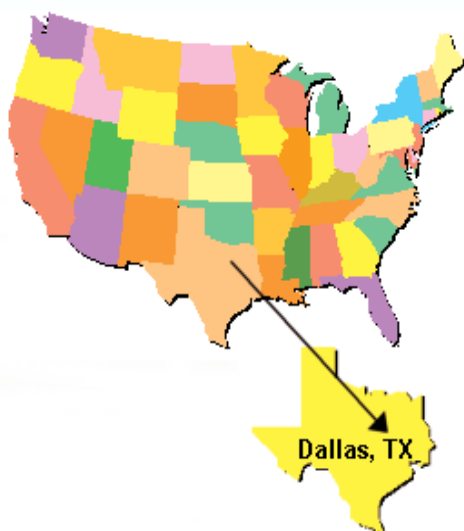
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ABOUT THE UNIVERSITY OF TEXAS SOUTHWESTERN

UT Southwestern, located 10 minutes outside of downtown Dallas, was established in 1943 as Southwestern Medical College and became part of The University of Texas System in 1949. In 1972 it was expanded into a full-fledged health science center, was eventually renamed The University of Texas Southwestern Medical Center at Dallas (UT Southwestern). More than 2,000 research projects are being conducted at UT Southwestern. In addition to the important work being done on HALT-C, UT Southwestern is also involved in basic and clinical studies in cancer, neuroscience, heart disease and stroke, arthritis, diabetes and many other fields.



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