

NEWSLETTER



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Director/Neurologist
Dr. Victor Biton

Epilepsy RN
Judy Summers

Research Coordinators
Denise Davis
Donna Hemphill, RN
Dusty Holderfield, RN

Research Assistants
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Teri Walters
Betty Ussery

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Noel Franks

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Kristi Cox

STAY SAFE IN COLD WEATHER

Older adults can lose body heat fast—faster than when they were young. A big chill can turn into a dangerous problem before an older person even knows what's happening. Doctors call this serious problem **hypothermia** (hi-po-ther-mee-uh).

For an older person, a body temperature colder than 95 degrees can cause many health problems such as heart attack, kidney problems, liver damage or worse.

Diabetes, thyroid problems, Parkinson's disease or arthritis are common problems for older people. These health concerns can make it harder to stay warm.

Sometimes it is hard to tell if a person has hypothermia. It is important to look for warning signs.

Early signs of hypothermia

- Cold feet and hands

- Puffy or swollen face
- Pale skin
- Shivering
- Slower than normal speech or slurring words
- Acting sleepy
- Being angry or confused

Later signs of hypothermia

- Moving slowly, trouble walking or being clumsy
- Stiff and jerky arm or leg movements
- Slow heartbeat that is not regular
- Slow, shallow breathing
- Blacking out or losing consciousness

If you suspect that someone has hypothermia call 911. While waiting for assistance, wrap the person in a warm blanket. Do not rub the person's arms or legs. Do not try to warm the person in a bath or use a heating pad.

RESEARCH UPDATES

Valeant issued positive results from a phase II trial of **retigabine** for the treatment of epilepsy. The researchers found that partial-onset seizure frequency decreased in a dose-dependant manner: 23% for 600mg/day, 29% for 900mg/day and 35% for 1200mg/day, compared to 13% for placebo. The most common adverse effects were

drowsiness, dizziness, confusion, speech disorder, vertigo, tremor, amnesia, abnormal thinking, abnormal gait, skin irritation and double vision. Retigabine is currently undergoing international phase III trials.

UCB finished phase III trials for **Keppra**, finding the drug significantly reduced the frequency of partial onset

To stay warm at home it may be helpful to close off any unused room. Close the vents and shut the doors in these rooms. Place a rolled towel in front of all doors to keep out drafts. Make sure the house isn't losing heat through the windows. Keep blinds and curtains closed. Use weather stripping or caulk to close gaps around the windows. Wear warm clothes during the day even inside the house and use extra blankets at night. Wear loose layers outside on chilly days. Wear a hat, scarf and gloves. Don't stay out in the cold and wind for a long time.

(Alzheimer's Arkansas Programs and Services Newsletter—January 2007)

seizures in children from one month to less than four years of age.

Neurochem reported negative results from a phase III trial of **Alzhemed** for the treatment of Alzheimer's disease. Treatment with Alzhemed did not demonstrate a statistically significant improvement over placebo.

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RESEARCH UPDATES CONTINUED...

Transition and **Elan** released positive results from several phase I trials of **ELND-005/AZD-103** for the treatment of Alzheimer's disease. Treatment was safe and well-tolerated at all doses and dosing regimens examined, with no reported adverse events. They plan to commence phase II trials by the end of 2007 or early 2008.

Neupro has been approved for the treatment of Parkinson's disease. Developed by

Schwartz, Neupro is specifically indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease. Neupro is supplied as a patch in 2, 4 and 6 mg. It is designed to provide rotigotine, a non-ergoline dopamine agonist, continuously over a 24-hour period. The most common side effects included skin reactions at the patch site, dizziness, nausea, vomiting,

drowsiness and insomnia, most of which are typical of this class of drugs.

The phase III trial of **safinamide**, designed to treat Parkinson's disease symptoms, ended, and **Merck Serono** found supplementing a stable dose of single dopamine agonist with safinamide resulted in the improvement of motor symptoms in subjects with Parkinson's disease.

Faust reported positive results from a phase IIa trial of **FP0011** for the treatment of Parkinson's disease. Treatment was well tolerated and symptoms showed positive improvements. Phase IIb trials are being planned for the near future.

Newron reported positive results from a phase II trial of **ralfinamide** for the treatment of neuropathic pain. Treatment was generally safe and well tolerated at the highest dose tested. They recently received

approval for the commencement of U.S. based trials.

Avigen posted positive interim results from a phase IIa trial of **AV411** for the treatment of neuropathic pain in Australia. Treatment was well-tolerated, with all adverse events mild to moderate in nature and pharmacokinetic data support a twice daily dosing profile. They are planning U.S. based trials pending the IND approval.

Biogen and **Elan** reported positive results from two phase III trials of **Tysabri** for the treatment of multiple sclerosis. Tysabri led to statistically significant improvements compared with a decline in the placebo group. Tysabri was recently approved by the FDA.

Helicon reported positive preliminary results from a phase IIa trial of **IPL 455** for the treatment of age-associated memory impairment.
Continued on pg. 3

"If you want to make important discoveries, work on important problems"

- P.B. Medawar

"Hope Through Research"



"The wisest mind has something yet to learn"

-George Santayana

Together, we can fight
DIABETIC NEUROPATHY PAIN.



If you're a diabetic who's experiencing tingling or burning foot pain, you can participate in a research study to evaluate an investigational pain medication that is unique in how it affects pain.

To learn more, please contact:

Clinical Trials, Inc.
501-227-6179

Local doctors are now evaluating an investigational pain medication to help treat foot pain associated with diabetes.

To pre-qualify for this research study, a person must:

- Be 18 years or older
- Have a medical diagnosis of type-I (insulin dependent) or type-II (non-insulin dependent) diabetes
- Be experiencing pain due to chronic diabetic neuropathy for at least 6 months, with the primary pain location being in the feet

All qualified participants will receive study-related treatment and the investigational pain medication at no cost. Reimbursement for time and travel may also be provided.

Additionally, all participants who complete this study will receive access to this novel, investigational pain medication for one full year.

Taking Medicines Correctly

It's important to take your medications exactly as your doctor prescribes to keep yourself healthy. It's also important to talk to your doctor about the medications you take.

- Talk often with your doctor, pharmacist, home health nurse or other healthcare providers
- Tell them your current medications and dietary supplements, including vitamins and herbs
- Describe any problems or side effects you have with your medications
- Never be hesitant to discuss your concerns and ask questions
- Understand why you are taking each medication
- Know your medications by name, recognize what they look like and know how and when to take them
- Read medication labels carefully & follow the directions

Alzheimer's Disease

affects nearly half of those over 85—with an estimated 4 million cases in the United States alone. By 2050, that number is expected to reach 14 million.

We are now looking for volunteers to participate in a clinical research study to treat Alzheimer's disease. You may be eligible to participate if you:

- ☞ Are 55 years old, or older
- ☞ Are diagnosed with Alzheimer's disease
- ☞ Are in otherwise good health



- Get help if you have trouble understanding any of the directions
- Check the date to make sure the medication is not out-of-date

Work with your doctor to develop a schedule to remind you when and how to take your medications. You can use charts and notes to help. Your doctor may give you a printed form but you can also write down a list that includes: Names of all your medications, what they are for, how much you take, when you take them and any special directions.

(Source: Aging Arkansas, March 2007)

CURRENT STUDIES

Epilepsy

- Cluster seizures
- Epilepsy—uncontrolled even after years of treatment with AED's (anti-epileptic drugs).

Diabetic Neuropathy

- Type 1 or 2 Diabetes, DPN (tingling, burning, numbness) in your fingers, hands, toes or feet.

Alzheimer's Disease

- Probable Alzheimer's disease, 50+ years of age and may or may not be on medication.

FOOD AND HEALTH

Some foods are bad for your teeth but some foods are actually good for your dental health.

Rebuild enamel—Yogurt, cheese, and milk are good sources of calcium. Calcium helps tooth enamel and strengthens the bone around your teeth. Calcium also deflects natural acids in your mouth and helps prevent decay.

Boost gum health—Grapefruit aids in wound healing, decreases gum bleeding, and prevents the collagen network in your gums from breaking down and loosening around your teeth. However, the acid can temporarily reduce the strength of your tooth enamel, so dentist recommend waiting at least 30 minutes after eating grapefruit to brush your teeth. Grapefruit also interacts with some medications,

so check with your doctor first.

Bust bacteria—Kiwis, oranges, limes, cranberries, and strawberries are rich with vitamin C—a killer of oral bacteria. Green tea contains catechins that kill bacteria in the mouth. Spicy foods such as wasabi have phytochemicals than inhibit the growth of germs.

Smell sweeter—mint and parsley kill bacteria in the mouth and some herbs naturally freshen breath.

Stop stains—cauliflower, spinach, lettuce and broccoli are sources of minerals that help prevent red wine, cola or coffee stains from penetrating the enamel. Strawberries have elements to brighten your smile. Raw vegetables stimulates saliva which neutralized acids and strengthens teeth.

(Source: AARP, Oct. 2007)

Research Updates

Continued from Page 2

Avanir received good news upon completion of its phase III trial of **Zenvia**, an NMDA antagonist and sigma-1 agonist for diabetic neuropathic pain. Subjects treated with Zenvia reported lower pain ratings than subjects given placebo.

(Source: Applied Clinical Trials—June, August 2007, CW Weekly—February-September 2007)

National Memory Screening Day

November 13th
501-227-6179

*appointments required

Call Clinical Trials, Inc. for more information.

501-227-6179

info@clinicaltrialsinc.com



Visit our website:

www.clinicaltrialsinc.com

"We Believe in
HOPE THROUGH
RESEARCH"

Clinical Trials, Inc.

2 Lile Court
Suite 100
Little Rock, AR 72205

POSTAGE
HERE

At Clinical Trials, Inc., our mission is to provide "Hope Through Research." Our multi-disciplinary organization consists of a medical team that facilitates quality clinical research, provides superior patient care, and utilizes cutting edge technology and treatment.

Some of the benefits of participating in a clinical trial include access to new treatments that might work better than existing therapies, medical care and follow-up care at no cost, and the knowledge of benefiting science.

MAILING LABEL HERE

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Research"*



Phone: 501.227.6179

Fax: 501.221.3426

Email: info@clinicaltrialsinc.com

**"Science is
organized
knowledge.
Wisdom is
organized life"
-Immanuel Kant**

A PERSONAL EXPERIENCE...

WITH EPILEPSY by John Miers

Nothing upsets parents more than learning that one of their children has a health-related problem.

When confronted by an illness in one of their children, parents have a wide range of responses, from caution and concern to profound fear. This is even more likely if the problem is due to something that they don't really understand, such as epilepsy. Parents can become overprotective when their child with epilepsy wants to try a new activity, like swimming or riding a bicycle, if the parent believes that there could be a real danger involved in the activity.

Having a seizure can change a child's life in dramatic ways, and set a child apart from friends and siblings. It can be confusing when the only consistent parental message seems to be that he or she isn't "allowed" to do many things that friends and siblings can do. Sometimes, a child with epilepsy may be teased or believe that this will be the case. In addition, having epilepsy usually means multiple medical tests, many doctors visits, and possibly medications.

I've been there, too. When I was a baby, I had several

seizures. The doctor reassured my parents that I would be fine. But, when I was twelve, I had another seizure. My mother, being a nurse, took me to a pediatric neurologist, who again reassured us that I would be alright—"if it didn't happen again." It did happen again. My seizures became gradually more frequent. First every six months, then every three months, and, by the time I was in college, I was having seizures monthly. My epilepsy became harder to live with, but I got used to it—sort of. While I had the good fortune of never being teased, I still did not feel quite whole. My seizures are still not controlled, but I have an understanding and helpful family.

What advice can I give about what to say to your child with epilepsy? Every single person is a unique combination of strengths and weaknesses. Be frank and honest about what is going on, what needs to be done, and what should not be done. Doing this can be a difficult and perplexing because parents want to urge their children to do as much as they can, while being aware of specific activities that may pose a threat. Parents and

children need to be cautious, but not overwhelmed with fear. Often the physician or health practitioner working with your child can help in setting appropriate limits.

For many people their seizures are controlled through medication, surgery, special diets, or just over time. While some people do seem to grow out of their seizures, others seem to grow into them. For children and parents, as well as physicians, the uncertainty of possible outcomes is challenging.

What can we tell other adults? Most of all, we need to tell them that it is O.K. for our children to play together. We can explain that a child may have a seizure sometime, and show them how to handle a child with a seizure.

We also need to ensure that our children also know about their epilepsy, including what they can and cannot do, both now and in the future. It is important to be optimistic. The challenges that we face will change through time, requiring both parents and children to keep abreast of the emerging issues in epilepsy diagnosis and treatment.

- John G. Miers of Bethesda, MD
Married with 3 daughters and 1 grandson

Retired from a federal agency as the Office of Diversity and Employee Advocacy Programs Director.