

# CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center, Inc.

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Tel. (505) 855-5525

Fall 2002

Vol. 5, No. 4

## Hormone Replacement Therapy— Good News & Bad News

If you have watched TV or read a newspaper lately, you have probably seen something about a new research study on hormone replacement therapy for postmenopausal women. The study is called the Women's Health Initiative (WHI). This is a huge undertaking that enrolled 161,809 postmenopausal women at 40 clinical centers in the US between 1993 and 1998.

The portion of the study getting all the publicity involved 16,608 women who had not had hysterectomies. Half were given Prempro (estrogen + a type of progesterone) and half were given a placebo (sugar pill). They were monitored for the development of cardiovascular disease, cancer, and fractures. The study was stopped on May 31, 2002, several years before its scheduled completion date, because of concern that the risks of taking the medication outweighed the benefits. This is where the good news and the bad news comes in.

The good news is that the study supported the long-held belief that estrogen reduces the risk of fractures. Also, the treated group developed less colon cancer than

the placebo group.

The bad, and very surprising news, is that treated patients had more strokes, heart attacks, blood clots, and breast cancer. Researchers concluded that this treatment should not be started or continued for the purpose of preventing coronary heart disease.



To understand the nuances of this probably requires an advanced degree in biostatistics, but here are some numbers that may be helpful. Of the women receiving treatment, 97.5%

had none of these problems. If 10,000 women were treated for a year, there would be an extra 7 heart attacks, 8 strokes, 8 breast cancers, and 18 blood clots per year. This additional risk is large in terms of percent increase compared to not taking the drug, but small in proportion to the total number of women who are treated and do have not a problem. Strictly speaking, these results apply only to women taking Prempro or its equivalent, not other forms of hormones. If you are taking hormones, or thinking of starting, talk to your healthcare provider for more information.

See back page of this newsletter for more on estrogen.

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## ***Clinical Research***

*Our clinical research program is recruiting patients to participate in studies to test new medications and evaluate new uses for currently available drugs. By participating in a study you will have the opportunity to use one of these medications, have free examinations and tests, and receive reimbursement for your time and travel. If this interests you, please take a few minutes to read the major criteria for participation.*

*If you think you may qualify for a study, ask for Valerie White, the Research Manager, or call the Research Dept. at (505) 855-5505.*

*Feel free to pass this newsletter to a friend or relative who may be interested. The drug study information will be updated quarterly, since we are continually starting new studies and closing out old ones. If there is nothing for you now, there may be next time.*

### **Once a Year Treatment - Postmenopausal Osteoporosis**

This is a clinical research study to evaluate the effectiveness and safety of a once a year intravenous dose of an investigational medication in reducing the risk of fracture in postmenopausal osteoporotic women. You may qualify for this 3-year trial if you meet all study entry criteria.

Qualifications:

Postmenopausal women, ages 65 to 89, and

Can currently be taking Hormone Replacement Therapy / Estrogen Replacement Therapy (Selective Estrogen Receptor Modulator's) or calcitonin, and

Not taking oral bisphosphonates, fluoride, tibolone or parathyroid hormone, and

No bilateral hip replacement or use of hip protectors, and

Meet all other entry criteria.

### **Treatment of Postmenopausal Osteoporosis**

The purpose of this study is to compare placebo and an investigational drug in the prevention of spinal fractures in postmenopausal women. Qualified participants will receive study medications, calcium and vitamin D supplements. Study-related health assessments include physical, bone density tests, spine X-ray, gynecologic exam and mammogram. There are several screening visits to determine eligibility,

and every 6 months for up to 5 years.

Qualifications:

Ambulatory postmenopausal female, age 60-80,

Anatomy suitable for DXA,

BMD -2.5 to -4.0,

No corticosteroids > 30 days within past year, and

No use of estrogen/progestin containing implants, ever.

### **Postmenopausal Osteoporosis**

This is a clinical research study designed to compare two currently marketed drugs for the treatment of osteoporosis in postmenopausal women on the chance of experiencing fractures. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 5 years. Compensation up to \$300 is available to qualified

participants. Qualifications:

Females 50-80 years of age, and

At least 2 years postmenopausal, and

No spinal fractures, and

Have not used estrogen replacement therapy (hormones) within the last month, and

Have no history of cancer, and

Meet all study entry requirements.

### **Postmenopausal Osteoporosis**

This is a clinical research study designed to compare the efficacy and safety of monthly versus daily oral administrations of an investigational drug in women with postmenopausal osteoporosis. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 24 months. Compensation is available to quali-

fied participants. Qualifications:

Women ages 55 - 80

At least 5 years postmenopausal

No malignant disease diagnosed within the previous 10 years

No breast cancer diagnosed within the past 20 years

No allergies to bisphosphonates

Meet all other criteria

## Osteoarthritis Research Study

This is a clinical research study designed to evaluate the safety, tolerability and effectiveness of an investigational medication in patients with osteoarthritis. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 12 months. Compensation for your time and travel expenses is available to qualified participants for study participation.

Qualifications: Male or female, at least 50 years of age, clinically diagnosed with OA of the knee, hip, hand or spine; No concurrent medical or arthritis disease, e.g., rheumatoid arthritis; No uncontrolled hypertension; No allergies to aspirin, diclofenac sodium, other NSAIDs, and COX-2 selective inhibitors; Have not donated blood or plasma within the last four weeks; and Meet all other entry criteria.

## Migraine Headache

This is a clinical research study designed to evaluate the effectiveness and safety of zonisamide as prophylactic treatment in subjects with migraine headaches. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 20 weeks. Compensation is available to qualified participants for study participation. Quali-

fications: Male or female, 18-65 years of age. Have at least 4 migraine attacks per 28 days, each attack separated by 48 hours. Do not use more than 3 different medications for control of a single migraine within 3 months. No allergy to sulfonamides (sulpha-based medication).

## Type 2 Diabetes Mellitus

This is a clinical research study designed to determine the efficacy, safety, tolerability, and pharmacokinetics of an investigational drug in patients with type 2 diabetes mellitus. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 18 weeks. Compensation is available to qualified participants for study participation.

Qualifications: Male or female, 35 to 75 years of age Diagnosed with type 2 diabetes mellitus more than 3 months. No uncontrolled hypertension. No heart attack within last 6 months. Women cannot be pregnant or lactating and must be using an acceptable form of contraception.

## Breast Density in Premenopausal Women

This is a clinical research study designed to determine if the application of an experimental drug (4-OHT Tamoxifen gel) will improve the reading and interpretation of your mammogram by decreasing breast density (whiteness in the film). You may qualify for this 6-month trial if you meet all study entry criteria.

Qualifications: Premenopausal women ages 18-45 50% - 80% density in breast tissue by mammography. Normal menstrual cycles. No hormones or steroids within the last 3 months. No breast surgery within the last 2 years, and meet all other entry criteria.

# Calendar of Events

Osteoporosis Foundation  
of New Mexico  
is proud to sponsor the

Osteoporosis Support Group

Free  
Educational  
Presentations

Second Thursday of Every Month

Rehabilitation Hospital  
of New Mexico  
(formerly St. Joseph  
Rehabilitation Hospital)

Pinch Room  
505 Elm St NE  
Albuquerque, NM 87102  
1:30 PM - 3:30 PM

Thursday, October 10, 2002  
George Fraser, PT  
The Do's & Don'ts of  
Physical Activity

Thursday, Nov. 14, 2002  
Lance A. Rudolph, MD  
What Men Need to Know  
about Bones

Thursday, Dec. 12, 2002  
David Valentine  
The Hidden Secret  
Behind Osteoporosis  
(with a special interactive session  
and holiday celebration)

The support group is open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want.

**Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS**

**Dear Dr. Lewiecki— This question is about my mother. She is 73 years old, and has been taking estrogen since she went through menopause at the age of 51. I have heard that hormones can be dangerous. Should she stop taking them? Suzanne B., Bernalillo, NM.**

A recent research study has shown that treatment with Prempro, a combination of estrogen and a type of progesterone, is associated with a small but significant increase in the risk of stroke, heart attacks, blood clots, and breast cancer. Benefits of treatment are reduced risk of osteoporotic fractures and colon cancer. For someone already taking hormones and doing fine, like your mother, it is natural to wonder about the necessity and the safety of continuing treatment.

No medication, including hormones, should be taken unless the benefits outweigh the risks. Estrogen is not the Fountain of Youth, but it is certainly the best medication for treating menopausal symptoms, such as hot flushes. Once a woman is

past the time of having menopausal symptoms, it may no longer be necessary to take the hormones.

This is what I suggest for some of my patients. If it is not clear that hormone therapy is necessary, I will slowly decrease the dose over a period of a few weeks and then stop. If no problems develop, then it is fine to stay off hormones. If prevention or treatment of osteoporosis is a concern, there are a number of other medications that are very effective and do not have the same risks as estrogen.

Now back to your mother. She should not make any change in her medication without first discussing it with physician. She needs to consider why she was given estrogen in the first place, and whether there is still a reason to take it now. No medication should ever be taken unless there is a good reason to do so, and the risks of treatment are acceptable.

*Mike Lewiecki*

**RISK & BENEFIT**

When you buy life insurance, you are risking the premium that you pay for the benefit of providing your survivors with some level of financial security when you die. When you take a medication, you usually have a good understanding of the expected benefits (better control of diabetes, or reduced risk of osteoporotic fracture, for example), but risk is a little harder to understand.

Scientists often use the terms absolute risk and relative risk. With hormone replacement therapy (HRT) in the WHI study (see cover story), the absolute risk of having a stroke in one year is x in 10,000, or .xx%. Most would consider this a low risk. On the other hand, the relative risk is xx% higher than in women not taking HRT. This sounds like a high risk.

What does this mean? Is HRT risky, or not? From the point a view of an individual patient the risk is small, and perhaps acceptable. From a public health perspective, if millions of women are taking HRT, even a small increase in individual risk can add up to a large number of women with a catastrophic event, such as stroke. For a woman who is taking,, or considering taking HRT, a decision must be made after thorough discussion with a healthcare profession, considering the expected benefits of taking the drug, and the known side effects, or risks.

**OSTEOPOROSIS FOUNDATION OF NEW MEXICO**

**The Osteoporosis Foundation of New Mexico needs your support! This is a local non-profit 501(c) (3) foundation established to benefit osteoporosis research and education. Please consider making a tax-deductible donation or bequest. Donations may be mailed to Osteoporosis Foundation of New Mexico at 300 Oak St. NE, Albuquerque, NM 87106. For more information, call Yvonne Brusuelas, Executive Director, at (505) 855-5627. Visit the foundation website at:**

**[www.osteoporosisfoundationnm.org](http://www.osteoporosisfoundationnm.org)**

### **Constipation-Predominant IBS**

This is a clinical research study designed to evaluate the effectiveness and safety of an investigational drug, Dexloiglumide, in female patients with constipation-predominant irritable bowel syndrome. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 16 weeks. Compensation is available to qualified participants for study participation.

**Qualifications:**  
Females 18-70 years of age.  
2 years postmenopausal, surgically sterile or practicing acceptable method of contraception.  
No daily use of laxatives or laxative abuse.  
No abdominal surgery (exception appendectomy or cholecystectomy).  
Generally in good health.

### **Research Study of Postmenopausal Women with Low Bone Density**

This is a clinical research study designed to determine the efficacy, safety, and tolerability of an investigational drug for postmenopausal women with low bone mineral density. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 2 years. Compensation is available to qualified participants for study participation.

**Qualifications:**  
Women not more than 85 years of age.  
At least 1 year postmenopausal.  
No bisphosphonate use within the last 12 months.  
No hormone replacement therapy, selective estrogen receptor modulators, and certain other medications used within last 6 months.  
Meet all other entry criteria.

### **Insomnia Research Study**

This is a clinical research study designed to assess the long-term safety and efficacy of a new investigational drug in adult patients with primary insomnia. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 8 months. Compensation is available to qualified participants for study participation.

**Qualifications:**  
Male or female, 21 to 64 years of age.  
Three months history of primary insomnia.  
Have used or are currently using sleep aid medications at least four times per month.  
No significant illness.  
No sleep disorders, e.g., sleep apnea, narcolepsy.  
Meet all other entry criteria.



## **Woman to Woman**

by  
Julia Chavez, CNP

## **Do You Have an Overactive Bladder?**

Overactive bladder is not normal at any age.

If you have sudden urges to go to the bathroom to urinate or have to go frequently, it may be due to a bladder infection or several other conditions, including diabetes.

If you have to get up at night more than two times to urinate, or if you have wetting accidents, it may be due to a condition called overactive bladder. This is easily treatable with medication.

Women who have borne children may have weak bladder muscles. It is important to discuss all potential medical conditions with your healthcare provider.

## Medical practice continues to grow for Julia Chavez, CNP

*Julia has adjusted well with her move from Espanola to Albuquerque. She is enjoying life in her new professional and personal environment, and thanks all of you for helping her.*

*Now that more and more people have discovered that she is an experienced and compassionate healthcare provider, her medical practice is growing fast. As busy as she is, she is still able to see urgent problems with patients of Dr. Lewiecki and Dr. Rudolph, and her own patients as well.*

*If you or a friend are looking for a primary healthcare provider, please consider Julia. She if you have not yet met Julia, please stop in to say hello. She will be happy to take a few minutes from her regular duties to talk with you. She sees all types of adult patients, with a special interest in women's healthcare.*

## High Cholesterol Research Study

This is a clinical research study designed to compare the efficacy and safety of an investigational medication that may help reduce cholesterol to two approved cholesterol-lowering medications to achieve the current nationally acceptable cholesterol levels in high-risk subjects with high cholesterol. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 18 weeks. Compensation is available to qualified participants for study

participation.

Qualifications:

Male or female, 18 years of age or older

Willing to discontinue all cholesterol-lowering drugs

No uncontrolled hypertension or hypothyroidism

No cyclic hormone replacement therapy

No active liver disease or hepatic dysfunction

Meet all other criteria

## Hypertension Research Study

This is a clinical research study designed to see whether one approved hypertension medication is more effective than another hypertension medication in lowering blood pressure. If you meet all study entry requirements you may be eligible to participate. The study will last approximately 8 to 10 weeks. Compensation is available to qualified participants for study participation.

Qualifications:

Male or female, 18 years or older

Mild to moderate hypertension

No night shift workers who routinely sleep during the day

Generally in good health

Meet all other criteria

## Anorexia Nervosa

This is a clinical research study designed to evaluate the effect of an investigational drug on bone mineral density in pediatric subjects with anorexia nervosa. If you meet all study entry requirements you may be eligible to participate. The study will last approximately 13 months. Compensation is available to qualified participants.

Have symptoms consistent with anorexia nervosa

No longer having menstrual cycles

Non-smoker or smokes  $\leq 15$  cigarettes per day

No recent history (within 12 months) of alcohol or other substance abuse

Must have parental consent

Meet all other requirements

Qualifications:

Females, under 17 years of age