CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

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

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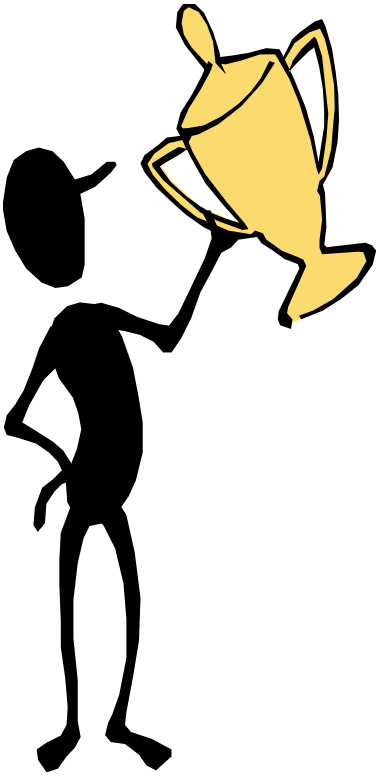
Research Center Receives International Award

The New Mexico Clinical Research & Osteoporosis Center has been notified that it is the recipient of an award for outstanding performance in a multi-national clinical trial for the treatment of osteoporosis.



The award is being presented by the University of California San Francisco, which coordinates clinical activities in four global regions– North America, Latin America, Europe and Asia-Pacific.

In a recent interview, Dr. Lance Rudolph, Research Director of the center, stated, "I am pleased to have the opportunity to participate in the development of new treatments for osteoporosis, and honored that our center has been recognized for the hard work of all our staff. We will continue our efforts to find better ways to manage this debilitating disease"

Osteoporosis or bone loss that can lead to fractures is a major public health problem that can result in disability or death. Researchers are now investigating new drugs given at less frequent dosing intervals and new ways of combining drugs that may ultimately offer greater patient convenience and increased effectiveness in reducing the risk of fractures.

Prevention of any disease is always preferable to treatment. The beast way to prevent osteoporosis is to do everything possible to achieve maximum "peak bone mass"- the highest level of bone density you can have. Peak bone mass, usually occurring in the 3rd decade of life, is determined by genetics and by lifestyle.

Regular exercise during the teenage years, as well as adequate daily intake of calcium and vitamin D, can increase the odds of reaching the maximum possible genetic potential. Having a high peak bone mass is like money in your retirement plan, and both will help you to enjoy your golden years.

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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.

Postmenopausal Osteoporosis

This is a clinical research study designed to compare the safety, toleration and efficacy of an investigational drug verses a marketed drug for the prevention of bone loss in postmenopausal women. If you meet all study entry criteria you may be eligible to participate. The study will last approximately two years. Compensation is available to qualified participants.

Qualifications:

Females, **48 to 75 years of age**
At least four years postmenopausal
No use of estrogen or estrogenic compounds within 3 months prior to screening
No history of osteoporotic fracture (including fracture of either hip) or any other recurrent fractures
Generally in good health
Meet all other entry criteria.

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.

Osteoarthritis and Rheumatoid Arthritis Research Study

This is a clinical research study designed to evaluate the safety of an investigational medication in patients with osteoarthritis or rheumatoid arthritis. If you meet all study entry criteria you may be eligible to participate. 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 osteoarthritis or rheumatoid arthritis
No concurrent medical or arthritic disease, e.g., inflammatory arthritis
No congestive heart failure
No uncontrolled hypertension
No allergies to aspirin, diclofenac sodium, other NSAIDs, and coxibs
Have not donated blood or plasma within the last four weeks
Meet all other entry requirements

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 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

Hypertensive Diabetics

This is a clinical research study designed to evaluate the safety and efficacy of the addition of amlodipine to quinapril or losartan in the treatment of diabetic hypertensive subjects. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 22 weeks. Compensation is available to qualified participants.

Qualifications:

Male or female, age 35 to 80 years

Diagnosed with Type 2 Diabetes, on stable treatment for at least 3 months

HbA1C ≤ 9.0

Have hypertension and not on OR must be willing to wash out of anti-hypertensive medication

No heart attack, coronary artery bypass, or intra-coronary interventions within 6 months

No donation of blood / blood products for transfusion 30 days before, during, or 30 days after treatment

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 weeks. Compensation for your time and travel expenses is available to qualified participants for study participation.

General Qualifications:

Male or female, at least 40 years of age, clinically diagnosed with OA of the knee or hip

Must be taking an NSAID or acetaminophen for at least 25 out of the previous 30 days

No concurrent medical or arthritic disease, e.g., rheumatoid arthritis

No uncontrolled hypertension

No allergies to acetaminophen, aspirin, ibuprofen, and other NSAIDs

Have <u>not</u> donated blood or plasma within the last four weeks

Generally in good health

Meet all other entry criteria

Calendar of Events

Osteoporosis Foundation of New Mexico

<u>Albuquerque Osteoporosis Support Group</u>

Free Educational Presentations

Second Thursday of every month

Rehabilitation Hospital of New Mexico

(formerly St. Joseph's Rehabilitation Hospital)

505 Elm St NE

Albuquerque, NM 87102

1:30 PM - 3:30 PM

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Treating Osteoporosis

▶Thursday, July 10, 2003

E. Michael Lewiecki, MD, FACP

"New Treatments for Osteoporosis"

▶Thursday, August 14, 2003

Keith Harvie, DO

"Calcium-"The Myth of Coral Calcium"

▶Thursday, September 11, 2003

Kristine Bordenave, MD

"Osteopenia, Osteoporosis, and Compression Fractures"

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

Consider attending if:

You have osteoporosis,

You have a loved one with osteoporosis, or

You are interested in learning more About osteoporosis.

Call 338-6333 to RSVP your attendance!

Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS

Dear Dr. Lewiecki– I have been on medication for osteoporosis for over a year, and my doctor just told me that my bone density went down. I am afraid I will end up stooped over like my mother. What should I do?
Martha D., Cedar Crest, NM.

The ideal response to drug treatment for osteoporosis is an increase in bone density, which is usually associated with an increase in bone strength and a reduction in fracture risk. However, bone density does not increase in every patient being treated for osteoporosis.

Studies have shown stability, or no change in bone density, can reduce the risk of fractures. If bone density goes down, as in your situation, that is cause for concern.

The first step in your evaluation is to determine whether the loss of bone density is a true biological change, and not a measurement error, an invalid comparison, or a statistically insignificant difference. The best assurance of this is to have well-trained and experience people doing the bone density test and interpreting the results. Certification by the International Society for Clinical Densitometry (ISCD) tells you that they have received special education in bone densitometry and passed a rigorous test.

Next, it is important that you are taking your medicine as directed, and that it is being absorbed into your body and getting to your bones. Also, you must be taking a sufficient amount of calcium and vitamin D for the medicine to work well.

Finally, you may have a disease, condition, or be taking another medication that has bad effects on your bones. There are simple blood and urine tests that can provide some very helpful information.

Depending on the results of your evaluation, you may need a different dose of your medication, a change in medication, or some additional treatment.

Mike Lewiecki

MALABSORPTION AND BONE DISEASE

Malabsorption refers to a condition where there is an abnormality in the absorption of nutrients from the intestinal tract. Examples of this are pernicious anemia, causing malabsorption of vitamin B12, and chronic pancreatitis, causing malabsorption of fats. Often there are symptoms, such as diarrhea and cramping, that accompany malabsorption problems.

Some types of malabsorption impair the ability of the intestinal tract to absorb calcium and vitamin D, resulting in increased risk of osteoporosis. An example is celiac disease, or celiac sprue. This is a common disease (1 in 133 Americans) that may cause no intestinal symptoms, yet still lead to the development of osteoporosis. It is treated with a gluten-free diet, which may result in large increases in bone density, even without medication. There are simple tests that can determine your risk of celiac disease.

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 Barbara Bayer, PhD, Executive Director, at (505) 338-6333. Visit the foundation website at:

www.osteoporosisfoundationnm.org.

Are You an Invisible Caregiver?

Do you worry about leaving mom or dad (or your spouse) at home alone? Do you help an older adult with any of the following tasks?

1. Preparing meals;
2. Bathing and getting dressed;
3. Managing medications;
4. Getting to doctors visits;
5. Grocery shopping;
6. Cleaning the house;
7. Paying the bills;
8. Any other task.

If you do any of the above, than you are a caregiver. A caregiver is someone who assists another person-usually a family member-who has physical or mental limitations. Caregiving is a labor of love which can be very rewarding, but there may be times when you need a little break or emotional support.

If this sounds familiar, you are not alone, but more importantly there is help for you. There are numerous resources available in our community. Our staff has recently become involved with a UNM project called "Making the Link."

We have brochures with telephone numbers and information to help you make the link. Ask any staff member.

We care about our patients and their caregivers.

Woman to Woman

by
Julia Chavez, CNP

Migraine?

Do you get a headache that lasts 4-72 hours, is throbbing, is moderate to severe in intensity, is on one side, becomes worse with exertion, and is associated with nausea, vomiting, or sensitivity to light, sound, or smell?

If you have three or four of the above criteria, then you are probably experiencing a migraine. Migraines are more common in women than in men and the cause is unknown, but several triggers are recognized. Cycling estrogen, a significant trigger, may explain why there are three times as many women with migraines as men. Other triggers include insomnia, barometric pressure change, and hunger.

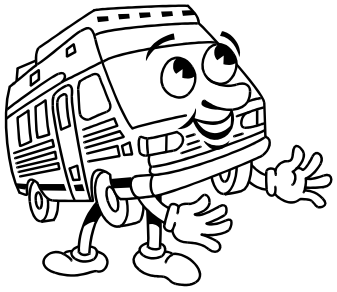
Migraines may be preceded by a short period of depression, irritability, restlessness, or anorexia, and may be associated with an aura. An aura is a passing, reversible, neurological deficit which can be visual, sensory, muscular, or language related. The migraine may be daily or once every several months. It is more probable when there is a family history of migraines. There are no useful diagnostic tests.

If you think you are experiencing migraines, you should discuss this with your provider.

On The Light Side

Well You Asked!

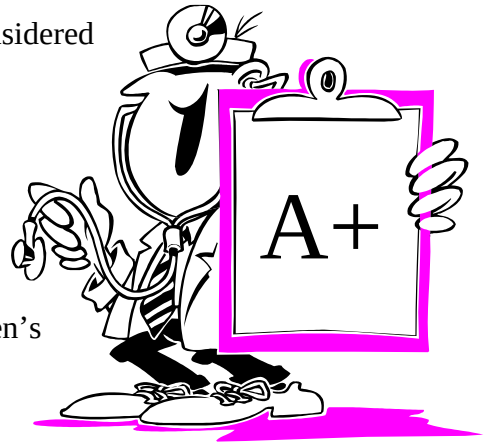
A resident began his examination of an elderly man by asking him what brought him to the hospital. The man looked at the resident and replied, "An ambulance."



The grand old man at the rest home was celebrating his 119th birthday, and the club reporter from the local newspaper asked him: "Tell me, to what do you attribute your long life?" The old man sighed, then said: "Well, I suppose it must be because I was born such a long time ago."

HOW MUCH DO YOU KNOW ABOUT OSTEOPOROSIS?

TEST YOUR KNOWLEDGE



1. Which of the following are considered weight-bearing exercises:
    a. Jogging
    b. Walking
    c. Stair climbing
    d. Dancing
    e. All of the above

2. Osteoporosis is strictly a women's disease.
    True / False

3. Osteoporosis is often called a "silent disease."
    True / False

4. The recommended amount of calcium per day is 1200-1500 mg for all adults.
    True / False

5. Which of the following are considered risk factors for osteoporosis:
    a. Caucasian or Asian
    b. Small body frame
    c. Family history of osteoporosis
    d. All of the above

Answers:

1. All of the above. Weight-bearing exercises are important for building and maintaining bone mass.

2. False. Osteoporosis is not strictly a women's disease, though it is less common in men. Today, 2 million men in the United States have osteoporosis, and another 12 million are at risk.

3. True. Osteoporosis is often called a "silent disease" because there are no symptoms, so you can't feel your bones becoming weak. Sometimes, you will not know you have thinning bones until a bone breaks.

4. True. The National Osteoporosis Foundation recommends 1200-1500 mg of calcium per day for all adults. There are about 1200 mg of calcium in 3 cups of low-fat yogurt, or 6 oz of cheddar cheese.

5. All of the above. Because bone loss usually occurs without symptoms, it's important to understand the factors that can contribut to thinning bones. Talk to your doctor or healtcare professional .

All study-specific information is IRB approved. To learn more about any study, call (505) 855-5505.