

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

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

300 Oak St. NE, Albuquerque, NM 87106

www.nmbonecare.com

Tel. (505) 855-5525

Summer 2002

Vol. 5, No. 3

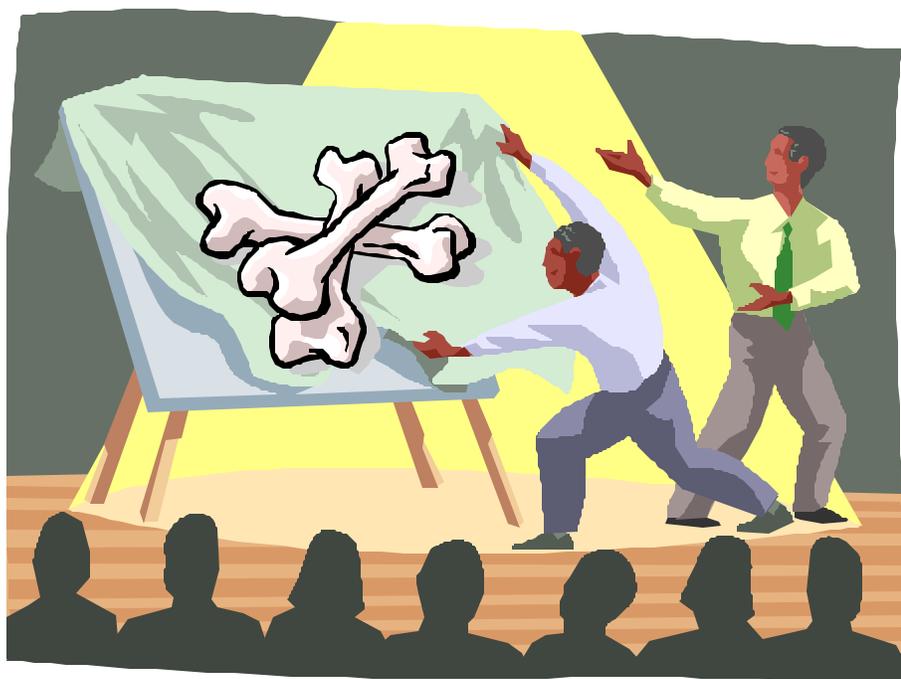
Learn About Your Bones

Knowledge is power. You have heard it before. This statement is often used in the world of finance and politics. It applies equally well to your healthcare. With regard to bone health, the more you know the better equipped you are to prevent and treat osteoporosis.

At New Mexico Clinical Research & Osteoporosis Center, we are deeply committed to educating ourselves about osteoporosis issues, and passing that knowledge on to our patients. We talk about osteoporosis every day during at the time of office visits and consultations. But how do you learn more about osteoporosis?

Here are four suggestions:

1. **Ask for our educational handouts** when you are in the office.
2. **Visit our web site** at www.nmbonecare.com. It has electronic versions of our office handouts and newsletters, information on meetings and seminars, and *Mike's Manual*, a book on the management of osteoporosis written for healthcare providers.
3. **Attend the Osteoporosis Support Group**, an educational meeting held the second Thursday of every month.
4. **Support the Osteoporosis Foundation of New Mexico**, a non-profit organization dedicated to educating New Mexicans about osteoporosis.



Staff

E. Michael Lewiecki, MD, FACP
Osteoporosis Director
Internal Medicine

Lance A. Rudolph, MD
Research Director
Internal Medicine

Julia R. Chavez, CNP
Adult Medicine
Women's Healthcare

Eric W. Best, MD
Internal Medicine

Yvonne Brusuelas
Management Director
Osteoporosis Ed. Coordinator

Valerie White, CCRC
Research Manager
Drug Study Coordinator

Sheri Romero, RT, CCRC
Drug Study Coordinator
Bone Densitometry Technologist

Phyllis Benavidez, CCRC
Drug Study Coordinator

Isis J. Martinez, CRC
Drug Study Coordinator

Ursula Lovato
Research Executive Assistant

Cheryl Champlin
Research Assistant

Julie Montano, RT, CDT
Bone Densitometry Technologist

Isabel Torres, RT
Drug Study Recruiter
Bone Densitometry Technologist

Deanna Reed
Patient/Billing Supervisor

Jeanette Ortiz
Bookkeeper

Janette Wiggins
Medical Assistant

Jessica Montoya
Medical Assistant

Anna Donner-Brownell
Medical Assistant

Marie Trujillo
Patient/Billing Coordinator

Rachel Varela
Patient/Billing Coordinator

Jeanie Gonzales
File Clerk

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.

Constipation-Predominant IBS

This is a clinical research study designed to evaluate the effectiveness and safety of an investigational drug, Dextroglumide, 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

Menopause, Estrogen Loss, and You.....

Baby boomers are becoming menopausal. Menopause can affect women in a variety of ways. Aging brings self-assuredness and a certain comfort with your role in life. It can also bring hot flashes, night sweats, vaginal dryness and irritation, loss of cognitive function, memory loss, changing moods, bone loss, and increased fracture risk. All of these have been proven to be a direct consequence of estrogen loss, and can be treated with estrogen replacement therapy (ERT).

The relationship between estrogen deficiency and cataracts, other eye conditions, cardiovascular disease, and overall mortality from heart disease is under investigation.

As with all medication, the use of ERT has benefits and risks. If you think you may be a candidate for estrogen replacement therapy, put it on the list of things to talk about at your next appointment.

Julia Chavez, CNP, thanks you for you for your support of her growing practice.

Julia has received a very warm welcome from friends, and patients in the Albuquerque area. We are very excited to have her as a member of our staff. Her caring manner and professional skills have already made her a popular choice. With her special interest in women's healthcare issues and clinical research, she is the perfect complement to our program of patient care. She has also been essential at providing coverage for the practice when Dr. Lewiecki or Dr. Rudolph is out of town.

If you or a friend are looking for a primary healthcare provider, please consider Julia. She is getting busier all the time, but still is able to take on new patients and "walk-ins." And, 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.

“It is an old axiom of mine that when you have excluded the impossible, whatever remains, however improbable, must be the truth.”



Sherlock Holmes, *The Beryl Coronet*

This well-known quotation is a favorite of many aficionados of Sherlock Holmes, or Sherlockians, as they are often called. The Sherlock Holmes stories were written by Sir Arthur Conan Doyle, a physician, and narrated by John H. Watson, MD. The four novels and fifty-six short stories about the world's most famous consulting detective are collectively called "The Canon." There are numerous references to physicians and medical disorders in these great works of literature. These stories ring so true for so many readers that it is sometimes debated whether Holmes was a fictional character or a famous historical figure.

We all have a bit of detective in us, and this holds especially true for physicians and other healthcare providers. Medical professionals are constantly looking for clues that will reveal the source of a patient's symptoms, unravel the nature of a disease, or help find a better treatment. At New Mexico Clinical Research & Osteoporosis Center, we could never hope to match the brilliance of Holmes, but we do the best we can. We try to recognize the needs of our patients, provide compassionate medical care, and do clinical research of the highest quality. We are proud that our research program has received national recognition on many occasions.

Each clinical trial that we do, and every patient we see, involves some clinical investigation, or medical mystery. We would not be far off the mark if we sometimes turned to Holmes for advice, as when he said:

“Let him, on meeting a fellow mortal, learn at a glance to distinguish the history of the man and the trade or profession to which he belongs. By a man's finger-nails, by his coat-sleeve, by his boot, by his trouser knees, by the callosities of his forefinger and thumb, by his expression, by his shirt cuffs— by each of these things a man's calling is plainly revealed.”

Sherlock Holmes, *A Study in Scarlet*

Prevention and Treatment of Steroid-Induced Bone Loss

This is a clinical research study to evaluate the effectiveness and safety of a research study drug given one weekly for the prevention and treatment of bone loss associated with the use of oral glucocorticoids, such as prednisone. This is a 12 month

long study.

Qualifications:

Man or woman age 18-80, and
Being treated with oral steroids.
Certain osteoporosis medications
are not allowed during this study.

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.

Qualifications:

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.
Meet all other entry criteria.

Calendar of Events

**Osteoporosis Foundation
of New Mexico
Osteoporosis Support Group**

**Free
Educational
Presentations
Second Thursday of every month**

**St. Joseph Rehabilitation Hospital
505 Elm St NE
Albuquerque, NM 87102
1:30 PM - 3:30 PM**

Thursday, July 11, 2002
Lauri Wilson, NM Dept. of Health
Topic: Bone & Joint Health
(Osteoporosis & Arthritis Health)

Thursday, August 8, 2002
Barbara Goldberg, RN
Topic: Feldenkrais
"Awareness through Movement"

Thursday, Sept. 12, 2002
Julia R. Chavez, CNP
Topic: Menopause, Estrogen Loss
and You

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.*

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki- I have been taking medication for osteoporosis for almost two years. My follow-up bone density test showed no improvement. Why isn't the medicine working?

Gabrielle C., Albuquerque, NM.

Your question is a very important one, because it raises some issues that are fundamental to the management of osteoporosis. It is important to keep in mind that the goal of osteoporosis treatment is to strengthen your bones and prevent fractures.

Physicians and patients like to see the bone density go up when medication is given. In general, an increase in bone density is associated with a decrease in the risk of osteoporotic fracture, and the greater the increase in bone density the greater the reduction in fracture risk. However, there is more to reducing fractures than just increasing bone density. This is illustrated by experience with medication, such as sodium fluoride, that causes very large increases in bone density yet does not reduce the risk of

fractures. Other medications, such as nasal calcitonin and ralifene, may cause very little change in bone density, yet still reduce the risk of fractures.

Researchers are now studying the non-bone density effects of osteoporosis medications. These are collectively called "bone quality." To learn more about bone quality, see the section on the right.

What about your situation? The fact that your bone density is stable (not decreased) may be a good result of therapy. Your bone density may have gone down if you were not taking the medicine. Studies have shown that patients who have a stable bone density when taking alendronate for osteoporosis had a reduced risk of fracture compared to those who lost bone.

The bottom line- Do not despair. You are probably doing fine. Keep taking your medication, and get enough calcium and vitamin D every day.

Mike Lewiecki

BONE QUALITY

The National Institutes of Health has identified four key components of bone quality- factors other than bone density that contribute to bone strength. These are:

Architecture. This refers to bone size and shape, and the internal microscopic structure of bone. A bone biopsy is required to find out what is happening inside your bones.

Turnover. Bone turnover is the metabolic activity of bone tissue, measured in tests such as Ntx or Ctx.

Microdamage. Microscopic fractures are probably occurring to all of us every day, and may eventually lead to loss of bone strength.

Mineralization. The amount of calcium in bone tissue is an important determinant of bone strength.

Treatment with an osteoporosis drug may influence any or all of these, in addition to its effects on bone density.

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.