

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

300 Oak St. NE, Albuquerque, NM 87106

www.nmbonecare.com

Tel. (505) 855-5525

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Worldwide Economic Crisis Puts Osteoporosis Care in Peril

The stock market crash, downturn in real estate values, and severe limitations in lending have affected all of us in one way or another. Skyrocketing health insurance premiums have contributed to the financial stress of individuals and businesses, with the federal government rightfully taking a serious look at healthcare reform. There is danger, however, that the baby (in this case, osteoporosis care) may be thrown out with the bathwater.

A 2004 report of the US Surgeon General identified osteoporosis as a major public health concern with serious consequences, including disability, death, and high costs due to fractures. The Surgeon General went on to say that osteoporosis is commonly not recognized when it is present, and commonly not treated. He challenged us all (doctors, patients, and health plans) to do better at identifying those of us who are at risk for fracture and see that appropriate treatment is given.

At the same time the Surgeon General is telling us to do more in caring for osteoporosis, other federal agencies and the private insurance industry are making it more difficult to do so. Medicare has reduced the reimbursement for bone density testing to a point that most facilities are not being paid enough to cover the cost of doing the test.

This has resulted in the closing of some facilities, with the eventual result that access to needed diagnostic services will be limited, with fewer patients being diagnosed with osteoporosis, fewer treated, and more fractures. Aside from the personal suffering caused by fractures, this has been estimated to cost Medicare (and the taxpayers) an extra \$1.1 billion in fracture-related expenses over the next 5 years. But there is more. Medicare and health plans do not cover bone density testing for all patients who need it, and are restricting the use of this test to monitor patients being treated. Other useful osteoporosis tests, such as the measurement of vitamin D levels and bone turnover markers (See side bar on back page) are now commonly being denied.

While efforts to contain out-of-control healthcare costs are certainly needed, restricting care that improves our health and saves money is not appropriate. Want to do something to help? Learn more and send an email to your senators and congressperson by going to the website of the International Society for Clinical Densitometry (www.iscd.org) or the National Osteoporosis Foundation (www.nof.org). Contact Medicare or your health plan if you are denied services you need. Support healthcare savings don't let the healthcare system deny essential services.

Staff

- E. Michael Lewiecki, MD**
Osteoporosis Director
- Lance A. Rudolph, MD**
Research Director
- Julia R. Chavez, CNP**
Adult Healthcare
- Eric W. Best, MD**
Internal Medicine
- Yvonne Brusuelas**
Management Director
- Valerie White, CCRC**
Research Manager
Drug Study Coordinator
- Devona Martinez**
Research Secretary
- Mary Jackson, BS**
Drug Study Recruiter Supervisor
- Sheri Romero, LRV, CCRC**
Drug Study Coordinator
- Karen Strickler, BS, CCT, CRC**
Drug Study Coordinator
- Adelaida Leal**
Drug Study Coordinator
- Roberta Pyszko, EMT/I**
Research Assistant
- Isabel Torres, RT(R), CDT**
Bone Densitometry Technologist
- Leslie Reynolds, RT(R)(M), CDT**
X-Ray Technologist/Recruiter
- Grace Chavez**
Drug Study Recruiter
- Michelle Benson, BA**
Data Entry Specialist
- Janette Wiggins**
Medical Assistant
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Medical Assistant
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Medical Secretary
- Rachel Varela**
Billing Assistant

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, call the Research Dept. at (505) 923-3232.

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.

Gout

An 8-week research study for an investigational medication for treatment of active gout flares. You may be eligible to participate if you are:

- Between the ages of 18 and 80
- Currently experiencing a gout flare for less than 5 days and
- Are unable or unwilling to use traditional treatments such as Indomethacin.

Novartis CACZ2255

IBS with Constipation

This is a randomized, placebo controlled study of an investigational medication to relieve the symptoms of Irritable Bowel Syndrome that is constipation predominant. You may qualify for this study if you are:

- Over the age of 18
- Have less than 3 bowel movements per week for at least the past month
- Have pain associated with your symptoms.

Forrest Lin-MD/31

Osteoarthritis of the Hip

This is a, randomized, placebo controlled study of an investigational IV treatment for the symptoms associated with osteoarthritis of the hip. You may be eligible to participate if you are:

- Over the age 18
- Have osteoarthritis pain in either the hip
- Unable to take NSAIDS or are getting inadequate relief from current NSAIDS (i.e. Ibuprofen, Celebrex or Naproxen), or are considering invasive treatments such as injections or replacement.

Pfizer OA

Hypertension

This is a randomized, placebo controlled study of an investigational medication in combination with an approved medication for the treatment of hypertension. You may qualify for this study if you are:

- Over the ages of 18
- Have high blood pressure controlled with less than 3 medications
- Have no history in the past 6 months of heart attack or stroke.

Takeda 491

Heartburn

This is a randomized, placebo controlled study of an investigational medication for Heartburn or Gerd. You may qualify for this study if you are:

- Over the ages of 18
- Take heartburn medication such as Prevacid or Nexium twice a day
- Have less than 1 episode of heartburn a week on your current medications

Takeda 178

Inhaled Insulin for Diabetics with COPD or Asthma

This is an open-label, randomized research study to evaluate the safety of an inhaled insulin in people with diabetes and mild COPD or asthma over a 12 month treatment program. You may qualify for this study if you are:

- Between the ages of 18 and 70
- Have type 1 or 2 diabetes and have not had to change diabetic medications in the past 3 months
- A non-smoker or have quit smoking more than 6 months ago.

MKC-TI-134

Pre-diabetes and Bone Health

A new study is looking at FDA approved diabetes drugs and how they affect bone health. You may be eligible to participate if you:

- Are a postmenopausal woman under the age of 70
- Have been told you have high blood sugar or are pre-diabetic or borderline diabetic
- Do not currently have osteoporosis.

Takeda

Osteoporosis

A 48-week research study of oral calcitonin vs. inhaled calcitonin vs. placebo in postmenopausal women with osteoporosis. You may be eligible to participate if you:

- Are a postmenopausal woman over 45 years of age
- Have osteoporosis and currently not be taking any bone medications such as Fosamax, Boniva or Actonel
- Not currently being treated with hormone replacement therapy.

Unigene

Osteoporosis

This is a 4-year study of an investigational medication vs. placebo in postmenopausal women with osteoporosis. You may qualify for this study if you are:

- Over age 65
- Have not broken a hip
- Have osteoporosis that is not currently being treated with medications such as Fosamax, Boniva or Actonel.

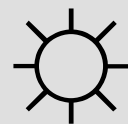
Merck -018

Why Should I Participate In A Clinical Trial?

As a volunteer in a clinical research trial you will not only take on an active role in your own health care but you will also:

- Participate in the development of medical therapies that may offer better treatments and cures for diseases.
- Gain access to new research treatments before they become publicly available in the marketplace.
- Receive closely monitored health care for your condition.
- May receive compensation for your time and travel expenses.

Whatever reason you chose to participate in clinical research, be assured that you are engaging in the advancement of medical treatments, therapies, and cures for chronic or life-threatening diseases.



OSTEOARTHRITIS RESEARCH STUDY



DO YOU HAVE PAIN FROM OSTEOARTHRITIS IN YOUR KNEE OR HIP?

If you are suffering with osteoarthritis of the knee or hip, then you may qualify to participate in a new research study for osteoarthritis.

Main requirements for participating in the study are:

- You are 18 years or older
- You have been diagnosed with OA of the knee or hip
- You have not found sufficient relief from, or have not tolerated, standard medication
- You meet study-required pain levels and health criteria

Participation in this study includes:

- A comprehensive study-related health evaluation
- Educational materials about osteoarthritis
- Investigational study medication

Study medication and study-related procedures will be provided at no cost to you.

CALL NOW:
1-888-STDY-4-OA
(1-888-783-9462)



NEW MEXICO CLINICAL RESEARCH
& OSTEOPOROSIS CENTER
300 CAK STREET ALBUQUERQUE, NM 87104

www.caresearchstudies.com



Do you have
osteoporosis?

Are you
concerned
that you do?

You may qualify for this clinical research study.

Participants are needed for The POWER Study, a clinical research study of an investigational study drug that may reduce your chance of breaking a bone, a common risk of osteoporosis.

You may qualify for this study if you:

- are at least 65 years old
- had your last menstrual period five or more years ago
- have never broken a hip

Eligibility will depend on a range of criteria.

Study participants will receive study-related drug and medical care at no charge.

Compensation may be provided.

For more information about The POWER Study, or to see if you qualify call
923-3232

or visit the website at www.nmbonecare.com

Do you have heartburn related to Gastroesophageal Reflux Disease (GERD)?

Do you take medication twice a day for it?

We are participating in a research study that will help determine if an investigational medication can control your heartburn related to GERD.

If you have GERD related heartburn that is controlled by taking medication twice a day you may qualify for this study.

To learn more, call:

923-3232

to speak to our study specialists

If you qualify you will receive study care and study medication at no cost
Financial compensation for time and travel may be provided



**Woman
To
Woman**
By
Julia Chavez, CNP

COULD IT BE DEPRESSION?

Depression is a feeling of intense sadness which may follow a recent loss or other sad or catastrophic event. It may persist beyond an appropriate length of time or be out of proportion to that event. Depression can cause sadness that is severe enough or persistent enough to interfere with daily functioning and may be accompanied by decrease in pleasure or activities. The exact cause is unknown but probably involves heredity, change in neurotransmitter levels, altered neuroendocrine functions or psychosocial factors. The diagnosis is based on history. Certain drugs can result in depressive disorders. Depression can cause poor concentration or fatigue. Other mental disorders can co-exist such as anxiety or panic attacks. It may reduce protective immune responses.

Diagnoses are based on identifying signs and symptoms. No laboratory findings are available to identify depression but they are necessary to exclude physical conditions.

Treatments usually consist of drug therapy or psychotherapy or both

**Osteoporosis Foundation
of New Mexico**

**Educational
Presentations**

Manzano Mesa
Multigenerational Center
501 Elizabeth SE
Albuquerque, NM 87123
(505) 275-8731

1:30 - 3:00PM

Quarterly in 2009:

February 19, 2009

Barbara Thorpe

Topic: "Vitamin D and Osteoporosis"

May 14, 2009

E. Michael Lewiecki, MD

Topic: "Update on Osteoporosis"

August 13, 2009

Shelley A. Rael, MS, RD, LD

Topic: "Nutrition and Bone Health
~more than Milk"

November 12, 2009

Elliot Pirece, MD

Topic: "Osteoporosis and Tips on How to
Treat Without Meds"

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want. There is limited space, so please sign up by calling 275-8731 in order to attend. A \$1 fee is collected in order to cover the cost of educational material.

Consider attending if:

- ❖ You have osteoporosis,
- ❖ You have a loved one with osteoporosis, or
- ❖ You are interested in learning more about osteoporosis.

If you enjoyed this newsletter and would like to be placed on an electronic mailing list, email ybrusuelas@nmbonecare.com. The newsletter is produced on a quarterly basis.



www.ofnm.org

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki– I read a lot about osteoporosis and keep seeing that weight-bearing exercise is recommended. The problem is that I don’t know what that means. Do I need to become a weight lifter? What can I do and what shouldn’t I do? I want to do all that I can to help with my bones, but I am confused.

Audrey P., Farmington, NM.

Dear Audrey – Exercise is good for all of us for many reasons, and almost anything you do is better than being a couch potato. Aerobic exercise (something that increases your heart rate and get you breathing hard) improves physical fitness, burns calories, reduces blood sugar and cholesterol levels, and gives an improved sense of well-being.

Weight-bearing exercise is particularly good for bones because it stresses them and stimulates their growth (at the microscopic level). It also improves muscle strength and helps with balance, which in turn may reduce the risk of falls and fractures that result from falls. The simplest form of

weight-bearing is walking. Doing this at a vigorous pace is better than a window-shopping pace, and jogging or high-impact aerobics may do even more. This helps with the bones in your legs and hips. Weight-bearing for the spine and upper body is also important. This can be done by using light weights, such as 5 pound dumb-bells, or even cans of soup, with arm curls and lifts.

What shouldn’t you do? For patients with osteoporosis, perhaps the most risky activities are those that involve extreme forward bending that places a lot of stress on the front part of the spine. Use good lifting technique by bending your knees and keeping your back straight when picking up a bag of groceries or a baby from the floor.

Whatever you chose to do for exercise, it should be something you enjoy and will be able to continue doing as you get older. It is also a good idea to vary the types of exercise so that you do not get bored with doing the same thing or do not get injured from repeatedly stressing the same part of your body. For more information, visit the website of the National Osteoporosis Foundation at www.nof.org.

Mike Lewiecki

WHAT IS A BONE TURNOVER MARKER?

One function of bones is to provide a structure, like the framework of a house, for attaching other important parts of the body. Bones certainly do this, but they do a lot more as well. While the framework of your house simply sits there and does its job, the bone has other functions, and keep working throughout your lifetime. Bone is the storage tank for calcium, so that when it is needed elsewhere, it can easily be retrieved and transported through your blood vessels. Bone also needs to repair itself when exposed to daily “micro-trauma” or less frequent fractures, or broken bones. Your skeleton is completely replaced every 10 years, something your house could never do by itself, by a process called bone remodeling.

The daily activity of bone remodeling produces chemical by-products, similar to the waste materials of a factory, that can be measured in the blood or urine. These small molecules (bone turnover makers) have names such as NTX, CTX, PINP, and osteocalcin. Measurement of one or more of these may help us to better understand why bone density is low, why you are not responding to treatment as expected, and whether the medication you are taking is being absorbed and doing what it is supposed to do to improve bone strength.



Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. Osteoporosis Foundation of New Mexico is a local non-profit 501(c)(3) foundation. Consider 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 at 505-855-5627.