# CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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## New Mexico Clinical Research & Osteoporosis Center is First New Mexico Facility Accredited for Bone Density Testing

New Mexico Clinical Research & Osteoporosis Center has been awarded accreditation from the Commission on the Accreditation of Skeletal Assessment Facilities (CASAF). It is the first and so far the only facility to in New Mexico to receive this accreditation. CASAF is international accreditation program developed by the Society International for Clinical Densitometry (ISCD).

In earning the CASAF accreditation, skeletal assessment facilities communicate to their community and patients that their facility has attained a significant measure of excellence in the provision of skeletal assessment services.

New Mexico Clinical Research & Osteoporosis Center is honored to receive facility accreditation from CASAF and is pleased to be recognized in the skeletal health assessment community for providing outstanding services in accordance with international standards and benchmarks in this field

"By applying for and receiving CASAF accreditation, New Mexico Clinical Research &

Osteoporosis Center has demonstrated a commitment to quality programs and services," said Dr. Ed Leib, CASAF Chair.

"Earning CASAF accreditation tells the Albuquerque community and potential patients that New Mexico Clinical Research & Osteoporosis Center has attained a measure of excellence and quality performance in this field."

New Mexico Clinical Research & Osteoporosis Center, Inc. is an organization dedicated to clinical research and the diagnosis and care of osteoporosis.

CASAF Accreditation Standards cover a wide variety of topics including personnel, DXA quality assurance and quality control, scan acquisition and analysis, scan interpretation and reporting, patient and referring physician education, privacy, business ethics and regulatory requirements.



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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, 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.

### Osteoarthritis of the Hip or Knee

An 18-week research study for an investigational medication for treatment of Osteoarthritis in the hip and knee. You may be eligible to participate if you are:

- Between 30 and 80 years old;
- Currently taking Tramadol or other pain medications for relief of hip and knee pain due to Osteoarthritis.

  NMT 1077-302

### **Treatment for Irritable Bowel Syndrome**

This is a 19-week study of investigation medication in female subjects with Diarrhea pre-dominant or alternating Irritable Bowel Syndrome. You may be eligible to participate if you are:

- A woman between 18 and 65;
- Suffering from abdominal pain or discomfort associated with diarrhea more than 3 days per month.

  VPI-TOFP-203

### Type 2 Diabetes and Bone Health.

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

- Are a postmenopausal woman between 55 and 80 years of age
- Have type 2 diabetes, being treated with diet and exercise alone or with one diabetes drug.
- Do not currently have osteoporosis.

AVD-111179

### 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 are pre-diabetic or borderline diabetic.
- Do not currently have osteoporosis.

Takeda

#### Diabetes

A research study to compare a new premix insulin with an approved premix insulin. You may be eligible to participate if you:

- Are between 18 and 80 years old
- Have taken insulin to control your diabetes for at least 1 year.

Roxane

### **Diabetic Neuropathy**

This is a 17-21 week study for an investigational medication for people suffering from pain associated with Diabetic Peripheral Neuropathy. You may be eligible to participate if you are:

- Diabetic over the age of 18;
- Experiencing pain tingling and numbness in your feet for at least 6 months.

### Osteoarthritis of the Hip & Osteoarthritis of the Knee

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

- Over the age 18:
- Have osteoarthritis pain in either the hip or the knee;
- 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 knee injections or replacement.

Pfizer OA

### **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

### **Chronic Constipation**

This is a randomized, placebo controlled study of an investigational medication to relieve the symptoms of chronic constipation or 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
   Forrest Lin-MD-01/31

# 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 lifethreatening diseases.



## PAIN IN YOUR BELLY?



Do you have chronic abdominal pain or discomfort? Is the pain accompanied by a change in your normal bowel movements? If so, you might have a medical condition known as Irritable Bowel Syndrome or IBS.

> We are looking for women with IBS to participate in a clinical research study of an investigational medication for IBS.

You may qualify for the study if you meet the following criteria:

- Between the ages of 18 and 65 years;
- Have been diagnosed or think you might have IBS
- Experiencing at least moderate abdominal pain or discomfort

Participants in this study will receive study medication, office visits, and study related medical procedures at no cost.

If you are interested in receiving more information, or to see if you qualify, please contact **New Mexico Clinical Research & Osteoporosis Center** at 505-923-3232.

Lance A. Rudolph, MD E. Michael Lewiecki, MD



## Woman To Woman

By Julia Chavez, CNP

## SHOTS, SHOTS, SHOTS

As summer fades and autumn colors come alive, comes the season to begin thinking about colds and influenza and pneumonia. A cold is caused by a virus and will usually run its course in a week or so. The symptoms will be runny or stuffy nose, sore throat, cough, mild headache, possibly a fever, or any combination of some or all of these symptoms. If the cold symptoms run longer than 7 to 10 days, bacteria may take advantage of the warm mucous and take over and in that case you may need an antibiotic.

The flu usually does not arrive until after November and sometimes not until as late as January or February. The flu is caused by a virus as well, but usually hits very suddenly as is accompanied by severe body aches as well as a high fever and the "cold" symptoms mentioned above. The best way to prevent a severe case of the flu is to get your flu shot.

### Flu Clinic:

We will be having walk-in flu shot clinics here every Thursday afternoon beginning October 16 through December 11, 2008 from 2 PM until 4 PM. This is for established patients only.

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.

## Osteoporosis Foundation of New Mexico

# **Educational Presentations**

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

1:30 - 3:00PM

### Last meeting 2008:

October 9, 2008 Barbara Thorpe Topic: "Vitamin D and Osteoporosis"

Quarterly in 2009: February 19, 2009

May 14, 2009

August 13, 2009

November 12, 2009

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.



www.ofnm.org

### OSTEOPOROSIS CORNER

### Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS

Dear Dr. Lewiecki— My doctor just told me I have osteopenia. What does this mean and how is it treated? Veronica G., Albuquerque, NM.

Dear Veronica – As with many words in the English language, "osteopenia" has more than one definition. When a radiologist uses this word after looking at an X-ray, it is a general term describing bones that appear to have less calcium in them than expected. However, in your case, I suspect that you had a measurement of your bone density with dual-energy X-ray absorptiometry (DXA) and that osteopenia was the diagnostic classification in the report. This means that you have a bone density value, expressed as a "T-score," that is between -1.0 and -2.5. If it were -1.0 or higher, it would be called normal, and if it were -2.5 or it would be called less, osteoporosis.

Patient with normal bone density almost never need to be treated with drugs, and those with osteoporosis almost always need to be treated with drugs. With osteopenia, some

patients should be treated and some should not. The challenge for doctors is to identify and treat patients who are at high risk for fracture. Since the range of T-scores that is called osteopenia may represent a wide range of fracture risk, from very high to very low, we need additional information to know what to do. We do this by considering "clinical risk factors." These are things other than bone density that determine the strength of your bones and the likelihood that they will break.

Examples of clinical risk factors include age (the older you are, the more likely you are to break a bone, even if bone density is the same), sex (women are more likely to break bones than men), previous fracture, current cigarette smoking, parent with hip fracture, and more.

There is a new way to evaluate fracture risk with computer program FRAX<sup>TM</sup>. This can be used with new treatment guidelines from the National Osteoporosis Foundation to determine which patients with osteopenia need to be treated. To learn more, see the column to the right.

Mike Lewiecki

### **FRAX**<sup>TM</sup>

The World Health Organization, with a little bit of help from New Mexico Clinical Research & Osteo-porosis Center, has developed a "fracture risk assessment tool" called FRAXTM. Anyone with a computer can go online at www.shef.ac.uk/FRAX to see what it looks like. By entering some simple information about bone density and answering a few questions, the program will cal-culate the 10-year probability of fracture. If you are a post-menopausal woman or man age 50 or older with osteopenia (T-score between -1.0 and -2.5), the National Osteoporosis Foundation recommends treatment to reduce fracture risk if the 10-year probability of hip fracture is 3% or greater, or if the 10-year probability of major osteoporotic fracture 20% greater is or (www.nof.org).

While FRAX<sup>TM</sup> can be a big help in deciding which patients with osteopenia need to be treated, it is also important to know when not to use it. FRAX<sup>TM</sup> does not help in deciding treatment if you are a premenopausal woman, a man under age 50, a child, or are already taking a drug for osteoporosis. Also, FRAX<sup>TM</sup> is not helpful if your bone density is normal or in the osteoporosis range.



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.