

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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Osteoporosis News for 2013

We can all look forward to new developments in the care of osteoporosis in 2013. Predicting the future is risky business, but here are some highlights on what to expect in the coming year.

Odanacatib (pronounced “oh-dan-a-CAT-ib”) is the generic name for an osteoporosis treatment that may become available in 2013. It is the first drug that is likely to be approved in a new class called cathepsin K inhibitors. Taken as a pill once a week, it reduces the activity of bone resorbing cells called osteoclasts. Cathepsin K is an enzyme produced by osteoclasts that dissolves bone protein. Since the activity of osteoclasts and the amount of cathepsin K is excessive in many forms of osteoporosis, inhibition by odanacatib serves to restore the balance of bone resorption and formation, thereby making bone stronger and less likely to break. If approved, odanacatib will be a welcome addition to the options for treating osteoporosis.

Another novel approach to treating osteoporosis may be whole body vibration. Up to now, studies on its effectiveness have given mixed results. However, a large study by Harvard researchers was recently completed, with the release of results expected this year. If the findings are favorable, it may spur further development of vibrating platforms. Standing on one of these devices transmits vibrations through the bones of the legs, potentially stimulating the activity bone

forming cells (osteoblasts). This could be a great benefit for those of us with impaired ability to walk due conditions such as stroke, spinal cord injuries, and multiple sclerosis. Stay tuned for results on this important development.

Finally, more hospitals and healthcare systems are developing “fracture liaison services” (FLS). This is a response to the well-recognized problem of far too many patients with fractures not being treated to reduce the risk of future fractures. With FLS, anyone hospitalized or seen in an emergency room for a low trauma fracture that might be due to osteoporosis is seen by a health educator, often a nurse. This person is the “liaison” whose duties are to educate the patient and family about the importance of exercise, calcium, and vitamin D in maintaining good bone health. Arrangements may be made for a bone density test and other tests to determine the cause of the osteoporosis. The results and suggestions for treatment can be shared with all the healthcare providers. The liaison could also check on the patient later to see that appropriate care has been started. There is now strong evidence from healthcare systems such as Kaiser in California and Geisinger in Pennsylvania that FLS can improve osteoporosis care, reduce the risk of future fractures, and save money. As knowledge of FLS expands, perhaps more hospitals and healthcare systems, including those in New Mexico, will start such programs for patients with osteoporosis.

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 Barton, CCRC

Research Manager/Drug Coordinator

Cheryl Harter

Research Secretary/Bookkeeper

Devona Martinez

Research Executive Assistant

Marlene Kravitz, BS, CCRC

Drug Study Coordinator

Karen Strickler, BS, CCT, CCRC

Drug Study Coordinator

Adelaida Leal, BBA, CCRC

Drug Study Coordinator

Michelle Garcia, BA, CCRC

Drug Study Coordinator

Dawn Jachter

Data Entry Specialist

Linda Weakland

Drug Study Recruiter

Debra Smigiel

Research Assistant

Isabel Torres, RT(R), CDT

Bone Densitometry Technologist

Janette Wiggins

Medical Assistant

Monica Tanny

Medical Assistant

Amanda Medina

Medical Assistant

Carrie Conger

Medical Assistant

Sandy Custer

Billing Supervisor

Loretta Morton

Medical Secretary

Roberta Ariaz

Medical Secretary

Elizabeth Valerio

IV Coordinator

Priscilla McManigal

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 or are interested in participating in a research study, call a study specialist 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. We do studies for high blood pressure, high cholesterol, osteoarthritis, osteoporosis, heartburn, GERD, irritable bowel syndrome and others. Please feel free to call and give your information to a study specialist for consideration for future studies. If there is nothing for you now, there may be next time.

Gout with Heart Problems

A research study comparing two approved medications for those diagnosed with gout who also have cardiac risk such as diabetes, previous heart attack or stroke:

- Are between 45 and 85 years old
- Suffering from gout whether or not you are currently taking daily medication

Restless Leg Syndrome

A clinical trial to assess the safety and efficacy of an investigational medication for restless leg syndrome. You may be eligible to participate if you:

- Are 18 years or over
- Have restless legs 15 or more times per month.

GSK-RLS-

Osteoporosis

A clinical trial of an investigational medication for Postmenopausal women with osteoporosis. The second 12 months, the study becomes an open label study and all patients will receive Prolia. You may be eligible to participate if you:

- A postmenopausal woman between 60 to 90 years old.
- Willing to take Calcium and Vitamin D

AMG

Constipation

A clinical trial to assess the safety and efficacy of an investigational medication for chronic constipation and abdominal bloating. You may be eligible to participate if you:

- Have abdominal bloating
- If you have 3 or less bowel movements per week.

Forest LIN-MD-04

Cholesterol and Coronary Heart Disease

A clinical trial of an investigational medication for Hypercholesterolemia with Cardiovascular risk for patients who are not adequately controlled on their statin therapy. You may be eligible to participate if you:

- Are 18 years or over
- Your current LDL is above 70.

Sanofi

Severe Asthma

This is a clinical trial to evaluate the effectiveness of a study drug on patients with moderate to severe Asthma. You may be eligible if you are:

- Between the age of 18 – 65.
- Currently taking fluticasone.

Cephalon C38072/3084

Irritable Bowel Syndrome - Diarrhea Predominate

A clinical trial of an investigational medication for patients with, Diarrhea Predominate Irritable Bowel Syndrome. You may be eligible to participate if you:

- Between the ages of 18 to 80.
- Diagnosed with IBS and diarrhea more than 25% of the time.

Furiex-IBS/Diarrhea



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

WHY A COLONOSCOPY?

Colon cancer in its early stages may not be associated with any symptoms. However, some of the signs and symptoms of the disease can include changes in bowel habits, including diarrhea or constipation or a change in the consistency of the stools. Rectal bleeding or blood in the stools can be another symptom. Persistent abdominal cramping or the feeling that the bowel hasn't emptied completely and /or weakness or fatigue and unexplained weight loss are also important signs that you may need to have a colonoscopy.

Colonoscopies are recommended every ten years in everyone over the age of 50 and in younger people who have a family history of colon cancer. If you have not had your colonoscopy yet and are procrastinating for any reason, do not put it off any longer. It could save your life.

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

1:30-3:00 PM

2013 Meetings

February 14, 2013

Dr. Keith Harvie

Topic: "Description of Pain with Osteoporosis"

May 9, 2013

Daniel Widholm, RT

Topic: "Bone Density Testing: A Survivors Guide to Getting You Through the Process"

August 8, 2013

Gloria Dryer

Topic: "Yoga for Osteoporosis"

November 14, 2013

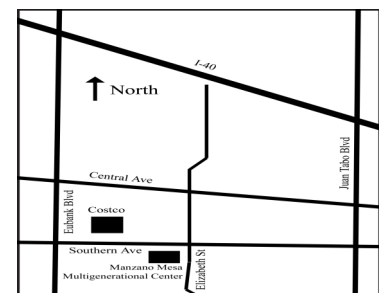
Dr. E. Michael Lewiecki

Topic: "New Treatments in Osteoporosis"

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.



Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki – My doctor told me I have osteoporosis and prescribed medication to treat it. I didn’t fill the prescription because of all that I have heard about side effects. I have a friend who takes strontium for her bones. I like the idea of something that is natural, but I don’t know anything about it. Should I take strontium?

Alice C., Albuquerque, NM.

Dear Alice – There is a drug called strontium ranelate (brand name: Protelos) that is approved in many countries, but not the US and Canada, for the treatment of osteoporosis. It is a proven treatment for women and men with osteoporosis. However, side effects have been reported, some of them serious. For example, an increase in the risk blood clotting has been observed. This drug should not be taken by anyone who is at high risk for blood clots. Rare but potentially life-threatening skin reactions have been reported, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms

(DRESS).

Strontium is a naturally occurring substance named after Strontian, Scotland, where it has been mined. When ingested and absorbed, it becomes incorporated into bone, where it increases bone density, at least in part because it has a heavier atomic weight than calcium. Being “natural” does not assure safety; after all, poisons such as arsenic and hemlock are also natural.

Strontium ranelate is a manufactured pharmaceutical product that is not available in the US. Other forms of strontium, such as strontium chloride and strontium citrate, can be purchased online and in many stores. However, the effectiveness and safety of these products have not been proven. Manufacturing is not subject to the same rigid standards as pharmaceutical products and the dose may not be exactly what is listed on the label. My advice is to stick with products are proven effective and safe.

Mike Lewiecki

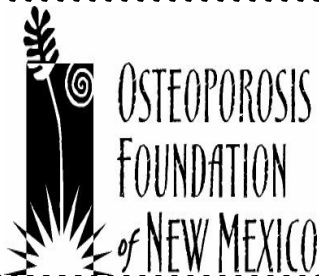
From the editor: If you have a question for Dr. Lewiecki, please send it by mail to the address on the front page of this newsletter or by email to mlewiecki@nmbonecare.com. It is not possible to respond to all questions submitted, but those that are of general interest will be considered for publication with an answer in future issues of this newsletter.

MEDICAL ADVERTISING AND SCIENCE

Many medications and nutritional products are extensively promoted through advertising in the news media. The purpose is to make you aware of a product and convince you to buy it. Advertising of FDA-approved drugs is highly regulated, requiring presentation of potential risks as well as benefits. Other products are less rigorously regulated, allowing unproven claims of benefits without presenting risks. With nutritional supplements, the benefits and risks may not be well understood.

Science, on the other hand, is a slow and painstaking process for understanding the world around us through careful observation and experimentation. Sometimes false claims are made and premature conclusions are reached, but in the long run we learn and make progress. Science has helped us improve our standards of living and lengthen our life expectancies, and also brought with it modern scourges such as pollution and horrible weapons.

With healthcare, as in other areas, we must do our best to distinguish between advertising and science. Whether it is calcium, a vitamin, a natural hormone, or a drug, consider what is known and what is merely claimed before buying and using it. While unproven claims may turn out to be correct and no serious harm may result, there is a balance of benefits and risks with everything we do.



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. www.ofnm.org For more information, call Yvonne Brusuelas at 505-855-5627.