

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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New Osteoporosis Treatment Approved

On June 1, 2010, the US Food and Drug Administration (FDA) announced the approval of Prolia (denosumab) for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Prolia is the first and only treatment that acts by inhibiting RANK ligand, the principal regulator of osteoclastic bone resorption. Approval of Prolia was based on the results of a large clinical trial (FREEDOM) conducted at research centers throughout the world, including here at New Mexico Clinical Research & Osteoporosis Center. FREEDOM showed that Prolia increased bone density and reduced the risk of vertebral fractures by 68%, hip fractures by 40%, and nonvertebral fractures by 20% in women with postmenopausal osteoporosis.

Prolia is administered as a 60 mg subcutaneous injection once every 6 months. The infrequent dosing and convenient method of administration makes this an attractive treatment for many patients, particularly for those with difficulties taking one of the oral bisphosphonates, such as Fosamax, Actonel, or Boniva.

The safety profile of Prolia is favorable. In FREEDOM, there was no increase in the risk of cancer, infection, cardiovascular disease, delayed fracture healing, or low serum calcium, and there were no cases of osteonecrosis of the jaw and no adverse reactions to the injection of Prolia. There was a

slight increase in the risk of some skin problems (eczema, serious cellulitis) in patients taking Prolia, while those taking Prolia had fewer falls and concussions than those on placebo.

Who is the kind of person who should be treated with Prolia? FREEDOM showed that it is good treatment for any postmenopausal woman with osteoporosis. However, many patients now begin treatment with generic Fosamax (alendronate) due to its very low cost. Others may be treated with Actonel, Boniva, or Evista. When those drugs cannot be taken due to other medical problems, or if side effects occur, or there is poor response to therapy, then something else must be used. Until now, the main choices have been injectable (IV) bisphosphonates—Reclast every 12 months or Boniva every 3 months. Both of these are excellent treatments for osteoporosis; both have been used and will continue to be used for many patients with osteoporosis. Prolia now provides another helpful option.

Prolia should be considered for postmenopausal women who need injectable therapy for osteoporosis. It is especially attractive for patients with veins that are difficult for inserting an IV catheter and for those who have reasons to avoid bisphosphonate therapy.

If you are doing well on your present treatment, there is no reason to change. If you think you might be a candidate for treatment with Prolia, see your healthcare provider for more information.

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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 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

This is a randomized placebo controlled study of an investigational medication used in combination with an approved medication or alone to lower uric acid, which causes gout flares. You may be eligible to participate if you are:

- Over the age of 18
- Diagnosed with gout

BCX

Gout Prevention

A six-month study to assess the prevention of gout flares when starting allo-purinol or other urate lowering therapy. You may be eligible to participate if you are:

- Over the age of 18 and have had a gout flare
- Are willing to start daily medication to prevent flares.

Regeneron

Diabetes

A research study of an investigational medication for diabetes. You may be eligible to participate if you are:

- Are a diabetic age 55-85 years old
- Your diabetes is not adequately controlled on your current regimen
- Do not have osteoporosis

JNJ-3010

Diabetes With COPD or Asthma

This is a research study of an inhaled insulin in diabetics with COPD or Asthma. You may be eligible to participate if you:

- Are a diabetic between 18 and 70 years old
- Are a non smoker
- Are currently taking medications to treat your diabetes

MKC-TI-134

COPD

This is a clinical trial to assess the safety and efficacy of an investigational inhaler. Study may last up to 4 years. Study related medication is provided at no charge and time and travel expenses are available for qualified participants. You may be eligible to participate if you:

- Are age 40 or over
- Have a diagnosis of COPD

BIPI 205452



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

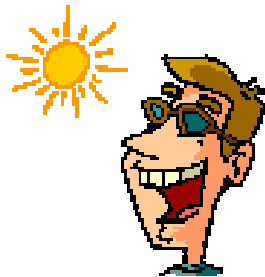
ENJOY THE SUNSHINE

Summertime is the time for enjoying the sunshine, but it can also mean painful over-exposure to the sun if not careful.

Time in the sun helps your body make more vitamin D and it is always good to keep up your level of activities, but it is important to limit your exposure to UV rays. The American Cancer Society offers a reminder about four key ways to protect you from the dangerous UV radiation. "Slip! Slop! Slap! And Wrap!" It stands for Slip on a shirt, Slop on sunscreen, Slap on a hat, and Wrap on sunglasses.

Sunscreens are not all the same so you need to choose one that is broad spectrum and has SPF of 15 or higher. You should apply it half an hour before going out in the sun and then every two hours while in the sun. If you go swimming, you need to re-apply it as soon as you get out of the water.

Enjoy your summer.



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
Quarterly:

February 18, 2010
Leona Rubin, MA
Topic: "My Active Life with
Osteoporosis"

May 13 2010
Joan Lewis, MD
Topic: "Osteoporosis,
the Silent Disease"

August 12, 2010
Jeff Rubin, chef/owner Savory Fare
Topic: "Add Calcium, not Calories"

November 12, 2010
Emil Faithe, MD

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

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki– I keep hearing that exercise is good for my bones, but I don’t know how to start. I have osteoporosis and want to do everything I can to make my bones stronger. After raising my three kids, I now have more time to take care of myself, but I don’t know where to start. Please help.

Janice C., Grants, NM.

Dear Janice – Regular physical activity is recommended for all of us and is especially important for bone health. Besides improving our physical fitness and burning calories, exercise may strengthen bones and helps with balance, making us less likely to fall.

Where to start? First, if you are in poor physical condition or have disabilities, such as arthritis or heart disease, check with your doctor before you start to see if you need any restrictions or medical evaluation before you start. Once you get the go-ahead to begin a fitness program, think of several activities that you enjoy. A good place to start for many of us is with walking. This is an excellent weight-

bearing activity that requires no membership fees, no special equipment other than comfortable shoes, and no athletic ability. Step out the front door and go. Walk with a neighbor, a friend, or your dog. Begin with a slow walk for a short period of time, but plan on slowly lengthening the distance and increasing the speed. How fast to go? Use the talk-test. If you cannot carry on a conversation, you are going too fast. How often? Plan for at least three times per week, but do more if you want.

There are many other forms of activity, depending on your interests. If you are interested in a gym, try one that has a trainer to help you get started. If you have special concerns or need extra professional help, consider a session with a physical therapist to help get started. Want some tips on things to do at home? Visit the website of the National Osteoporosis Foundation at www.nof.org for information on ordering a video with exercises for people with osteoporosis. Need extra help with balance? Try taking a yoga class or learn Tai-Chi. Remember, anything you do is better than nothing. Now go out and have fun!

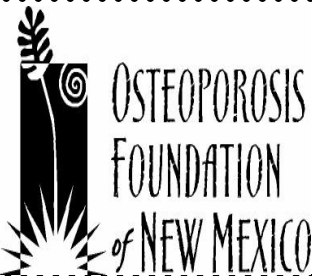
Mike Lewiecki

LESSONS FROM SPACE

There have been many technological advances or “spin-offs” from the US space program that have benefitted those of us who are not astronauts. These range from the development of a lifesaving heart pump for patients awaiting heart transplants to lighter and stronger bicycle helmets. Space flight has also taught us about the effects of zero-gravity on human physiology, particularly the skeleton.

Our bones are very sensitive to weight they are required to support. Here on earth, the skeleton develops according to the need to support our bodies under conditions of normal gravity. For an astronaut in space living for months under zero-gravity conditions, there is concern that rapid bone loss that could ultimately increase the risk of breaking bones. Experiments are underway on the International Space Station to mitigate bone loss with calcium, vitamin D, good nutrition, and exercise. Astronauts must come up with novel methods for “weight-bearing,” such as running on a treadmill while strapped down with bungee-cords.

It is easier to exercise on earth because, with respect to our bones, gravity is our friend. It provides just the right amount of load for us to get the benefit we need to have strong bones in the places they are needed most. So when you walk for your health, remember how much easier you have it than astronauts, who don’t have gravity to help them.



OSTEOPOROSIS FOUNDATION of NEW MEXICO

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.