

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

Winter 2009

Vol. 12, No. 1

New Ways to Make Bones Stronger

Osteoporosis is a disease that is characterized by reduced bone strength that results in increased risk of fractures (broken bones). The measurement of bone density is considered to be a surrogate of bone strength and fracture risk. In other words, when the bone density is low, the bones are weak and at high risk for fracture. Since fractures can be painful and result in long-term disability, loss of independence, and even death, we need to do all that is possible to prevent fractures. Although the risk of fractures can never be totally eliminated, there are things we can do to improve the odds.

Bone density in adults is determined by two factors- the peak bone mass (the best our bones ever were, usually occurring sometime in our 20s) and the rate of bone loss after that. To assure the best possible peak bone mass, a healthy lifestyle and good nutrition in childhood and adolescence are very important. To slow down the rate of bone loss later in life, we need to continue with regular physical activity and have a good intake of calcium and vitamin D. If osteoporosis or very low bone density is present, we may need medications to help. There are now many choices for osteoporosis medications, including a good one that is generic (very cheap!). However, scientists are continually searching for better and safer drugs to improve bone strength.

The recent trend in the drug treatment of osteoporosis is to use drugs that have long intervals between doses (now as long as one year) and that are easier to administer. Also, as we learn more about the workings of individual molecules that regulate the activity of bone cells, we have found new opportunities to develop new treatments.

One such drug that may be available for use by the end of 2009 is denosumab. It is given as a simple subcutaneous (just under the skin) injection once every 6 months. Research on this drug, conducted here at New Mexico Clinical Research & Osteoporosis Center and elsewhere, has shown that it makes bones stronger and less likely to break.

Another drug in development, odanacatib, is an inhibitor of an enzyme called cathepsin K. This enzyme, which is normally produced by osteoclast bone cells, dissolves the protein portion of bone in the process of bone remodeling. Since osteoporosis may be caused by excessive bone remodeling, a drug such as odanacatib that slows remodeling may improve bone strength and reduce fracture risk.

Other potentially useful drugs are ones that stimulate the formation of new bone in places where it has been lost. Researchers will continue to pursue all possible ways to improve bone strength and reduce the burden of osteoporotic fractures.

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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.

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

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

Chronic Constipation/IBS with 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

Osteoarthritis of the Hip or 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

Severe Heartburn or GERD

This is a 12 week study for an investigational medication for people suffering from severe heartburn or GERD. You may be eligible to participate if you are:

- Between 18 and 75;
- Experiencing heartburn symptoms at least twice a week for the past 3 months.

Eisai 301/303

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*

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:

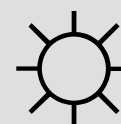
- Over age 65
- Have osteoporosis that is not currently being treated with medications such as Fosamax, Boniva or Actonel. *Merck -018*

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.



Why Should I Participate in Research?



As a volunteer in a clinical research trial you will:

- Help evaluate therapies that could lead to better treatments.
- Access new therapies before they become publicly available.
- Receive closely monitored health care for your condition.
- Receive compensation for your time and travel expenses.

Whatever reason you choose to participate in clinical research, know that you are helping in the advancement of medical treatments for chronic or life-threatening diseases.



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For More Information Call
923-3232 or visit

www.nmbonecare.com



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

Are Your Vaccines Up To Date?

You should get a flu shot every year. The flu can cause serious complications for people with chronic conditions or for people over the age of 65. The flu shot is recommended for people of all ages including healthy people but is most important for you if you have chronic or serious health conditions.

The pneumonia vaccine should also be taken by anyone with chronic conditions or for anyone over the age of 65. This vaccine will not protect against viral or atypical pneumonia but will protect you against the “worst” kind of pneumonia. This is a bacterial or pneumococcal pneumonia. You should have one vaccine followed by a booster approximately six years later. One you have taken the booster you will have lifetime immunity.

Zostavax (shingles) vaccine has been available for less than two years and is recommended for anyone over the age of sixty who has had the chicken-pox and who has never had shingles. It is a one-time vaccine at this time. Shingles is caused by the same virus that caused chicken-pox but stays dormant (asleep) in your nerve endings until it re-activates usually during a period of high stress. Shingles is typically extremely painful and is accompanied by a blistering rash.

If you are unsure of your vaccination status check with your provider.

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

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

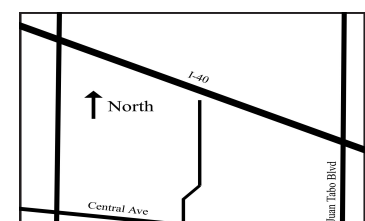
Elliot Pirece, MD

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.



Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki— I have osteoporosis. My mother also has osteoporosis. She broke her hip last year and is now in a nursing home. I am afraid of breaking bones, but I am nervous about taking drugs to treat my osteoporosis, since I keep reading in the paper about side effects they may cause. I don't know what to do. Please help. Lois B., Ruidoso, NM.

Dear Lois – While I can't give you individual medical advice without a consultation, I can give you some general information that may help you decide what is best for you.

To begin, anyone with osteoporosis should have a thorough evaluation to look for problems (such as hyperparathyroidism, celiac disease, or multiple myeloma) that may be causing it. Any problems that are found should be treated. You need to be getting some regular exercise, if possible, and enough calcium and vitamin D. Some simple lab tests can show whether the calcium and vitamin D is being absorbed normally. If you have not recently had a bone density

test, this may need to be done.

The National Osteoporosis Foundation has issued standard guidelines for the drug treatment of osteoporosis. The guidelines, which are based on strong medical evidence, clearly state that when osteoporosis is present, treatment should be given to reduce the risk of fracture. There are many drugs that are now available- alendronate (Fosamax and generic forms), risedronate (Actonel), ibandronate (Boniva), zoledronic acid (Reclast), raloxifene (Evista), calcitonin (Miacalcin, Fortical), and teriparatide (Forteo). They come in the form of pills (daily, weekly, or monthly), daily nasal spray (daily), intravenous injection (every 3 or 12 months), and daily subcutaneous injection.

Each of these drugs has been proven to reduce the risk of fractures, and each has possible side effects. Your doctor can review the risks and benefits of each of these drugs, considering your personal preferences, other medical problems, and other medications you are taking.

Mike Lewiecki

PREPARING TO SEE A DOCTOR ABOUT OSTEOPOROSIS

Although there are very few doctors who specialize in osteoporosis, many doctors take care of patients with osteoporosis. You can help your doctor to do a better job by preparing for your visit.

First, be aware that osteoporosis is a silent disease that causes no symptoms unless a fracture (broken bone) has occurred. Therefore, if you have aches and pains, as most of us do, it probably has nothing to do with osteoporosis.

Next, make some lists. Write down what you know about family members who have had osteoporosis or broken bones. If you have broken bones, write down what happened and when it happened. Make a complete list of medications you are taking, osteoporosis drugs you have ever taken, and if you had problems with them, what those were.

Finally, if you have had recent laboratory tests, bone density tests, or bone imaging (scan, CT, MRI, etc.) that the doctor does not already have, try to gather as much information about these as you can. Many patients now routinely ask for copies of their reports to keep a personal health file to show to other doctors they see. This can eliminate unnecessary duplication of tests, saving time and money.

By helping your doctor, you can help yourself to get the best possible medical care.



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.