

# CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

300 Oak St. NE, Albuquerque, NM 87106

www.nmbonecare.com

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## Inside Bones: How Osteoporosis Drugs Work

Osteoporosis is a disease that weakens bones and makes them susceptible to fracturing (breaking), sometimes with little or no trauma. If you have osteoporosis, you may be comforted in knowing that there are many medications that can make your bones stronger and reduce the risk of fractures. You are probably interested in the effectiveness, safety, convenience, and cost of taking medication. Physicians are interested in the same sort of issues, but usually think in terms of the balance between risk and benefit.

At New Mexico Clinical Research & Osteoporosis Center, we go a few steps further, since we not only care for patients with osteoporosis, but we are also involved with developing new treatments. In addition to thinking about the risk and benefit of drugs that are currently available, we have a strong interest in what makes bones strong, and what makes them break when they shouldn't. A thorough understanding of the causes of osteoporosis allows us to do a better job of finding new treatments.

We know that bone is more than a structure to keep our bodies from collapsing. The skeleton is an active organ that is continually being renewed through a process called bone turnover. This is done by the resorption or dissolving of bone in many small packets,

followed by replacement of new bone. When this process is out of balance (bone resorption exceeds formation), then osteoporosis eventually develops.

Medications that treat osteoporosis all have an effect on bone turnover, by either reducing bone resorption, increasing bone formation, or both. Most medications work by reducing bone resorption. These include Fosamax, Actonel, Boniva, Reclast, Evista, Miacalcin, and Fortical. They all increase the strength of the bone you have and reduce the risk of fractures. They are taken daily, weekly, monthly, every 3 months, or every 12 months, depending on the medication and the route of administration.

One drug, Forteo, is different than the others. It is classified as a bone-building drug. Forteo increases bone formation and builds new bone where bone has been lost. Its use is normally restricted to two years. Forteo is less convenient than the other drugs (it is given by daily self-injection, much the same as a diabetic taking insulin shots) and it is more expensive, but for the right patients it is the best drug.

Some exciting new drugs in development are targeted to individual molecules that control the process of bone resorption or formation. You will learn more about these drugs in future issues of this newsletter.

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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**

A 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:

- 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:

- 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:

- 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:

- 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:

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

*GSK PXN 110448*

## Osteoporosis & Kidney Function

This is a 1 year, randomized study of open label Ibandronate (Boniva) or Alendronate (Fosamax) in postmenopausal women with Osteoporosis at risk for renal disease. This study will compare the effects of different methods of administering the medication. **You may be eligible to participate if you are:**

- Over the age 65;
- Have been diagnosed with Osteoporosis;
- This study is open to women who have been previously treated for Osteoporosis.

*Roche BA 20341*

## IT'S A FACT — AGE AFFECTS A BODY



IF YOU ARE OVER AGE 65 WITH OSTEOPOROSIS OR LOW KIDNEY FUNCTION  
YOU MAY QUALIFY TO PARTICIPATE IN A CLINICAL TRIAL TO EVALUATE  
THE EFFECTS OF APPROVED OSTEOPOROSIS MEDICATIONS ON  
KIDNEY FUNCTIONS.

IF YOU ARE INTERESTED IN LEARNING MORE CALL

923-3232

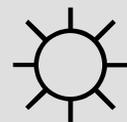
or visit [www.nmbonecare.com](http://www.nmbonecare.com)

## 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.



# Are Your Arthritis Pain Medicines Working? Joint Replacement Not An Option For You?



**NEW MEXICO CLINICAL RESEARCH & OSTEOPOROSIS CENTER IS CURRENTLY CONDUCTING A RESEARCH STUDY OF AN INVESTIGATIONAL MEDICATION FOR TREATMENT OF SEVERE OSTEOARTHRITIS IN THE HIP AND KNEE.**

**IF YOU ARE BETWEEN 30 AND 80 YEARS OLD AND ARE CURRENTLY TAKING PRESCRIPTION PAIN MEDICATIONS FOR RELIEF OF HIP AND KNEE PAIN DUE TO OSTEOARTHRITIS YOU MAY QUALIFY TO PARTICIPATE.**

**PLEASE CALL  
NEW MEXICO CLINICAL RESEARCH & OSTEOPOROSIS CENTER AT  
923-3232**

**or Visit [www.nmbonecare.com](http://www.nmbonecare.com)**

**COMPENSATION FOR TIME & TRAVEL IS AVAILABLE FOR QUALIFIED PARTICIPANTS**

**NEW MEXICO CLINICAL RESEARCH & OSTEOPOROSIS CENTER**

**300 Oak Street NE, Albuquerque, New Mexico 87106**

**E. Michael Lewiecki, MD**

**Lance A. Rudolph, MD**



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

**GET MORE FIBER IN YOUR DIET**

Foods that have been highly processed lose much of their fiber during the processing. It is important to get plenty of dietary fiber because it can help you lower your cholesterol and glucose as well as keeping your bowels regular and may even help you to lose weight.

Here are a few suggestions to help you boost the amount of fiber in your diet. Eat more raw vegetables and fresh fruit including the skins. Replace white bread, white rice, candy, cookies, and chips with whole-grain breads, brown rice, popcorn, fruits, and vegetables. Include high fiber foods in each meal. You can find many high fiber cereals such as oatmeal or bran cereals.

To avoid gas and bloating do not increase to high levels of fiber all at once. Do it gradually. Drink plenty of fluids to help your body handle the extra fiber. According to the FDA, food must contain at least 5 grams of fiber per serving to be considered high in fiber. According to the American Heart Association, you should eat at least 25-30 grams of fiber every day.

If you are concerned about adding fiber to your diet, check with your doctor.

**Osteoporosis Foundation  
of New Mexico**

**Educational  
Presentations**

2nd Thursday of every month:  
Manzano Mesa  
Multigenerational Center  
501 Elizabeth SE  
Albuquerque, NM 87123  
(505) 275-8731

1:30 - 3:00PM

July 10, 2008

Dr. Keith Harvi

Topic: "Treatment of Compression  
Fractures"

August 14, 2008

Dr. Viji Kumar

Topic: "To be determined"

Sept, 2008

Dr. Elliot Pierce

Topic: "Dianosing 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.

Consider attending if:

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



[www.osteoporosisfoundationnm.org](http://www.osteoporosisfoundationnm.org)

**Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS**

**Dear Dr. Lewiecki– I have been taking Fosamax to treat my osteoporosis for many years. Now my health plan wants me to switch to the new generic version. I know this is cheaper, but is it as good as Fosamax? Charlotte G., Durango, CO.**

Dear Charlotte – The generic term for Fosamax is alendronate. It is manufactured by many companies worldwide. Several of these products are now available in the United States, with more likely to follow in the future. In order for a generic drug to be approved by the Food and Drug Administration (FDA), it be proven to be “bioequivalent.” This is usually done by testing the generic product in several dozen healthy volunteers to determine whether the drug reaches the bloodstream and achieves similar concentrations compared to the brand name product.

Since the manufacturer of the generic product is not required to repeat the numerous research studies that were necessary to develop the original drug, it can be sold for

a lower price. This is good news for patients. Since generic alendronate is considerably less expensive than Fosamax, and may work about the same for your osteoporosis, it may be a good choice for you.

However, there are some potential concerns about generic alendronate that should be considered. Let me describe a few:

1. There may be counterfeit drug that is illegally sold as an FDA-approved generic product. You should only buy from reliable sources.
2. The bioequivalency that is proven in healthy volunteers may not necessarily apply to all patients.
3. Some studies have shown differences in pharmacological properties with generic versions, including esophageal adhesiveness and the pill’s dissolution/disintegration time.
4. Other studies have shown higher rates of side effects, such as stomach pain and heartburn, with generic alendronate.
5. Generic alendronate products are not all the same. Some may behave very much like Fosamax, and others not.

*Mike Lewiecki*

**WHAT IS GENERIC?**

The reader who wrote the question to the left of this column asks a question that raises a host of issues about generic drugs. The question we would all like to have answered is, “How good are generic drugs and can we really trust them?”

The FDA provides us with a high level of assurance that, in most cases, generic drugs can be used in the place of the more expensive brand name version. But generic drugs are not identical to the brand name version, and different generic versions of the same drug are not the same as each other. The size, shape, and color of the pill or capsule may be different. Although the active drug that is contained in the product must be the same, assuming that is is not counterfeit, there may be differences in filler material, stabilizers, and coloring. It is possible to be allergic to one or more of these materials in one version but not another. Other side effects, such as upset stomach or heartburn, may differ with different products due to differences in pharmacological properties of the product.

If you want to learn more about a particular generic product, ask your doctor for information.



**Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. The 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.**