How do osteoporosis drugs work?

All of the medications approved by the US Food and Drug Administration (FDA) for the treatment of osteoporosis have been proven to reduce the risk of fractures (broken bones). The way they work, called the “mechanism of action,” varies according to the type of medication. If you are taking one of these medications, you may want to understand how it works. Osteoporosis researchers spend their professional lives trying to learn more the root causes of osteoporosis in order to develop new treatments that might be more effective and safer than those we now have.

Since osteoporosis is usually caused by a higher than normal rate of bone metabolism (bone remodeling), most treatments are with drugs intended to slow the rate of bone remodeling back down to normal. These drugs are classified as “antiresorptive.” The antiresorptive drugs include the bisphosphonates (Fosamax, Actonel, Atelvia, Boniva, Reclast), Evista, and Prolia. These drugs typically increase bone density, or at least prevent bone loss, but do not build new bone in places where bone has been lost. Drugs that are bone builders are called “anabolic.” We currently have only one drug in this category- Forteo. However, much research is now underway to find new, and perhaps better, anabolic compounds.

Bisphosphonates are the drugs most commonly used for osteoporosis because they are highly effective and generally safe. Two of them (Fosamax and Boniva) are now generic, which has greatly reduced the cost. An interesting feature of the bisphosphonates is a long skeletal retention time. This means that after taking a drug of this type for many years, a lot will be stored in the bones and may still be effective if the medication is temporarily discontinued. This is called a “drug holiday.”

Evista has effects that are similar to estrogen is in some ways, such as being good for bones, but acts quite different than estrogen in other ways. For example, Evista reduces the risk of breast cancer and may be helpful in treating women with osteoporosis who are also at high risk for breast cancer.

Prolia is the first of a new class of agents for treating osteoporosis. It is an antibody that targets a single molecule regulating bone remodeling. It slows down the bone remodeling process and is given as an injection twice a year.

Forteo is the “big guerilla” for osteoporosis treatment. It is given as a self-administered injection once daily for a maximum of 24 months. It builds new bone and improves bone strength in ways that are totally different than the other medications. After finishing treatment with Forteo, it is important to switch to one of the antiresorptive medications to maintain the benefit it has achieved.

Side effects may occur as well, so take care to discuss these with your provider before starting.
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

Takeda TMX-67-301

**COPD**

A research study of an investigational medication for Chronic Obstructive Pulmonary Disease (COPD). You may be eligible to participate if you are:
- Are over age 40
- Are a current or ex Smoker

Forest COPD

**OSTEOPOROSIS**

A research study to estimate the percent of change in bone density in postmenopausal women previously treated with Alendronate. You may be eligible to participate if you are:
- Are you a postmenopausal woman between the ages of 55 and 85?
- Currently taking Alendronate.
- Willing to take Calcium & Vitamin D

Amgen 253

**Gout**

This is a study drug for gout. You may be eligible to participate if you are:
- A between the age of 18 - 85 years old
- And must be able and will to take Colchicine.

Ardea Light

**Healthy Women Osteoporosis Study**

This is a research study to study the effect of a medication on bones. You may be eligible to participate if you are:
- A postmenopausal women 45 to 75 years old
- Have not been diagnosed with osteoporosis
- Are at least 5 years post menopausal

Takeda 390104

**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

**Frequent Night Time Urination**

This is a clinical trial to assess the safety and efficacy of an investigational medication for Nocturia or frequent night time waking for urination. You may be eligible to participate if you:
- Are age 50 or over
- Wake more than twice a night

Serenity

All study-specific information is IRB approved. To learn more about any study, call (505) 923-3232
PROBLEMS WITH DIGESTION?

Have you ever wondered if you have gluten or wheat intolerance? Do the words celiac disease or sprue mean anything to you? All of these words describe the same malady, but no matter what you call it, it can make your life miserable. It is a chronic type of malabsorption syndrome and can have many ramifications. In some people it manifests as diarrhea or abdominal pain but in some people, it merely hinders absorption of food or nutrients or medicines. It can cause other problems due to this lack of absorption.

If you think you might have this problem, there are tests that can be done to verify. It requires some very special care in your dietary intake to keep it under control. There is a Celiac Sprue Association in Albuquerque that meets monthly and if you are interested, please discuss with us. Sometimes it helps to have a support group of people who understand what you are experiencing.

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

**Dear Dr. Lewiecki – I have been taking osteoporosis medicine for two years. My back pain has not gotten any better and my doctor just told me that my bone density has not changed since I started treatment. She wants to switch to another medicine, but I am worried that I wasted the last two years of treatment. Am I in big trouble?**

Yvonne P., Cedar Crest, NM.

Dear Yvonne – You may be fine. In fact, you may not even need to change your medicine. More information is needed to know for sure. But let me first say something about the back pain. Osteoporosis is a silent disease that does not cause back pain unless you have had a fracture. Most back pain is caused by other things, such as arthritis in the spine or disc disease. The treatment of osteoporosis cannot be expected to relieve back pain. You may need to have a few tests, including spine X-rays, if your back is giving you a lot of trouble.

The other issue concerns your bone density test. Most drugs used to treat osteoporosis produce an increase in bone density, but this does not happen to every single person who is treated. What is most interesting is that no change in bone density may actually be a good thing and represent a beneficial response to treatment. And if you had not been treated, it is likely that your bone density would have gotten worse.

We know from several research studies that women whose bone density remains the same with drugs such as Fosamax (alendronate) have improvement in bone strength and fewer fractures than comparable women who are not treated. You might ask, how can this be? It doesn’t make any sense, right? Doctors have scratched their heads about this as well.

Read the column to the right to learn more, but keep in mind that bone strength and fracture risk are determined by more than just bone density, and stable bone density may be a good response to treatment.

**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.

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**OSTEOPOROSIS TREATMENT RESPONSE**

The goal of treating osteoporosis with medications is to improve bone strength and reduce fracture risk. The possibility of breaking a bone can never be totally eliminated, since even the healthiest bone will crack if subjected to enough force. On average, osteoporosis medications cut the risk of breaking a bone in half. New medications are being developed that might do even better.

How can you tell if your osteoporosis medication is working? You can’t expect to feel any different. The best thing you can expect is nothing; that is, no broken bone. It is standard practice to monitor bone density, with the expectation that it will improve or at least remain stable. It may be a big disappointment to discover that there has been no change in your bone density after taking a medication for one or more years, but in most cases it is OK. After all, without the medicine your bone density would likely have gotten worse. Furthermore, research studies have shown that bones are getting stronger and fewer fractures are occurring in patients whose bone density remains the same on treatment. This is because of beneficial changes at the microscopic level inside the bones. These changes are not easily measured by a bone density test. We can see these changes with other tests, such as bone biopsies, that are part of research studies.

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.