

Injectable Medication for the Treatment of Osteoporosis

Why would anyone wish to have an injection instead of a pill? For the treatment of osteoporosis, there are several reasons. Some patients should not be taking certain osteoporosis medications due to esophagus problems that interfere with swallowing, or inability to remain sitting or standing for 30-60 minutes after taking the pill. For those who are able to take these pills, side effects such as upset stomach or heartburn may develop. For others, the pills may not work because of intestinal problems that interfere with the absorption of the pills into the bloodstream. Finally, it is now well recognized that many patients who start taking pills will stop them within the first year for many different reasons. The medical terminology for this is "poor adherence to therapy." Perhaps having a shot in the office at the time of a routine visit to the doctor every 3 months would be easier than remembering to take a pill every day, every week, or every month.



While injections are not necessary or desirable for most patients with osteoporosis, they could be a big help for some. The first injectable treatment for osteoporosis has recently been approved by the FDA (Food and Drug Administration).

The name of the drug is ibandronate (Boniva), the same as the monthly pill that has already been available for some time now. It is given as an injection into a vein over 15 to 30 seconds every 3 months. It should not be given to those with an allergy to the medication or any of its components, nor to anyone with severely abnormal kidney function, low blood calcium level, or vitamin D deficiency. Possible side effects after injection include flu-like symptoms that may last a few hours or days. If this occurs, it is most likely with the first injection, and typically does not occur or is much less severe after subsequent injections.

If you think an injectable treatment for osteoporosis might be right for you, ask your doctor for more information.

Staff

E. Michael Lewiecki, MD, FACP

Osteoporosis Director

Internal Medicine

Lance A. Rudolph, MD

Research Director

Internal Medicine

Julia R. Chavez, CNP

Adult Healthcare

Eric W. Best, MD

Internal Medicine

Yvonne Brusuelas

Management Director

Valerie White, CCRC

Research Manager

Drug Study Coordinator

Mary Jackson

Research Executive Assistant

Sheri Romero, LRV, CCRC

Drug Study Coordinator

Michele Dingman, BA, CCRC

Drug Study Coordinator

Aspen Montoya, CRC

Drug Study Coordinator

Donna Partington, LPN, CRC

Research Assistant

Isabel Torres, RT(R), CDT

Bone Densitometry Technologist

Ginnie Laroi-McClure, RT(R), CDT

Drug Study Recruiter

Alana Lohmann

Drug Study Recruiter

Janette Wiggins

Medical Assistant

Julianne Morris

Medical Assistant

Annette Berg

Medical Assistant/Medical Records

Lois Kollars

Billing/Bookkeeping Supervisor

Kim Fletcher

Billing Specialist

Stacey Escudero

Medical Secretary

Joe Ann Chavez

Medical Secretary

Would you like to receive this newsletter in electronic format?

There are two ways to receive this newsletter electronically: 1. Visit our website at www.nmbonecare.com to download the newsletter in PDF format, which you may then print on your home printer, or 2. To be placed on a list for automatic quarterly distribution of the newsletter as a PDF file attached to email, send your request to Yvonne Brusuelas at ybrusuelas@nmbonecare.com.

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, ask for Valerie White, the Research Manager, or 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.

Type 1 or 2 Diabetes Mellitus - Inhaled Insulin

This is a 2-year study to assess the safety of an experimental inhalation system for the treatment of Type 1 or 2 Diabetes Mellitus. Compensation is available to qualified participants.

You may qualify for this study if you:

- Are a non-smoking male or fe-

male aged 18 to 70 years

- Have been clinically diagnosed with Diabetes Mellitus Type 1 or type 2 for at least 2 years
- Are willing to keep all visit appointments

2274

Non-Surgical Pain Treatment for Carpal Tunnel Syndrome

This is an 8-week study to explore the use of a study patch that has a drug for pain already built into it. This means when the study patch is placed on the wrist, the study medicine is absorbed through the skin and directly to the pain in the wrist. You will be compensated for time and travel expense.

You may be eligible for participation:

- You must be 18 years of age or older

- You must be diagnosed with mild to moderate Carpal Tunnel Syndrome in one or both wrists
- You must be having symptoms of pain, numbness and/or tingling in the wrist(s).

2275

Hypertension

This is an 8 week study to evaluate the efficacy of Telmisartan in combination with Ramipril in patients with Stage I or II Hypertension.

Qualifications for this study:

- Must be male or female 18 years of age or older
- Women must be postmenopausal, surgically sterile or using birth control
- Must be able to discontinue current hypertension medications

- Must not be night shift workers and awake from 12am-4am on a regular basis
- Must be able and willing to comply with the study for its duration.

Reimbursement for time and travel is available to qualified participants.

2277

Heartburn Therapy

This is a 4-week study to evaluate the safety and efficacy of an investigational drug as a potential therapy for acid related disorders including Gastroesophageal Reflux Disease (GERD)

You may qualify for this study if:

- You are male or female at least 18 years of age
- Women must be postmenopausal for greater than 2 years, surgically sterile or using birth con-

- trol
- You have identified heartburn as your primary symptom
- You have a history of heartburn for 4 or more days during the 7 days prior to study day 1
- You have experienced episodes of heartburn for 6 months or longer

2270

Treatment of Heartburn or Acid Related Disorders

This is an 8-week study to evaluate the safety and efficacy of an investigational drug compared with FDA approved Lansoprazole as a potential therapy for acid related disorders including healing of Erosive Esophagitis

You may qualify for this study if you are:

- Male or female at least 18

- years of age
- Women must be postmenopausal for greater than 2 years, surgically sterile or using birth control

2271

Bone Quality in Women With Osteoporosis and Osteopenia

This is a one year clinical research study to assess the effect of monthly oral Ibandronate versus placebo on bone quality and strength at the hip in women with Osteoporosis.

You may be eligible to participate if you are:

- A postmenopausal woman age 55 to 85 at the time of screening
- Able to swallow a tablet whole
- Are free from gastrointestinal disease
- Able and willing to comply with the study for its duration.

2264

This is a one year clinical research study to assess the effect of monthly Ibandronate versus placebo on bone quality and strength in postmenopausal women with Osteopenia.

You may be eligible to participate if you are:

- Less than 3 years postmenopausal age 45 to 60 at the time of screening.
- Able to swallow a tablet whole
- Are free from gastrointestinal disease
- Able and willing to comply with the study for its duration

2267

**Osteoporosis Foundation
of New Mexico**

**Albuquerque Osteoporosis
Support Group**

**Educational
Presentations**

2nd Thursday of every month:
Downtown Osteoporosis
Support Group

Rehabilitation Hospital of New Mexico
(formerly St. Joseph's Rehabilitation
Hospital)
505 Elm St NE
Albuquerque, NM 87102
1:30 - 3:00PM



April 13, 2006
Dr. Arthur Bankhurst
"Risk Factors and Diagnosing
Osteoporosis"

May 11, 2006
Dr. E. Michael Lewiecki
"Everything You Ever Wanted to
Know About Osteoporosis"

June 8, 2006
Dr. Margaret Nolan
To Be Determined
##



The support group is 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.

To RSVP your attendance
call 338-6333

Type 2 Diabetes Mellitus

This is a 20-week study to evaluate the safety and efficacy of an investigational drug versus placebo in patients with type 2 Diabetes Mellitus.

You may qualify for this study if you:

- Are male or female age 18 - 79
- Have never received medical treatment for Diabetes

- Are able and willing to comply with the study for its duration
- Women must be post-menopausal, surgically sterile or using birth control

2276

When I Am Old—Author unknown

When I am old, I'll live with each kid
And bring so much happiness — just as they did.
I want to pay back all the joy they provided
Returning each deed. Oh, they'll be so excited!
When I am old and live with my kids.
I'll write on the walls with reds, whites and blues
And I'll bounce on the furniture, wearing my shoes,
I'll drink from the carton and then leave it out
I'll stuff all the toilets and oh, how they'll shout!
When I am old and live with my kids.
When they're on the phone and just out of reach
I'll get into things like sugar and bleach,
Oh, they'll snap their fingers and shake their head.
When they cook dinner and call me to eat
I'll not eat my green beans or salad or meat.
I'll gag on my okra, spill milk on the table
And when they get angry—I'll run, if I'm able.
And later, in bed I'll lay back and sigh
I'll thank God in my prayer and then close my eyes,
My kids will look down with a smile slowly creeping
And say with a groan, "She's so sweet when she's sleeping."



Woman to Woman

By
Julia Chavez, CNP

COLD OR ALLERGIES?

Colds and allergies may share some of the same symptoms, but they are very different diseases. Colds are caused by viruses and allergies are an immune system response caused by exposure to something you're allergic to such as pollen or pet dander. You can't "catch" an allergy from someone who has an allergy but cold viruses are easily spread from one person to another.

Cold symptoms can develop at any time and usually last from two to fourteen days. Seasonal allergy symptoms start at the same time every year and can last several months.

Treatment of a cold includes rest, pain relievers and over-the-counter cold remedies such as decongestants. Treatment of seasonal allergies may include over-the-counter or prescription antihistamines nasal steroid sprays and possibly, decongestants.

To help prevent allergy symptoms, avoid exposure to known allergens. To help prevent colds, wash your hands often or use antibacterial hand gels.

Colds usually have cough, sneezing, sore throat, runny nose and stuffy nose. Colds rarely have itchy eyes or fever. Allergies never have fevers or generalized aches and pains. They sometime have cough, fatigue and sore throat. They usually have itchy eyes sneezing and runny nose.

If you need help with colds or allergies see your medical provider.

Medicare Advantage...Is It for You?

With all the buzz about the new Medicare Drug Plans we are failing to see the silver lining--the much less talked about Medicare Advantage Plans. Certainly deserving of more discussion, this plan coverage (to Medicare Parts A and B) is probably the boldest change in Medicare since the 1960's. Older plans like Medigap Supplement Plans A-J ceased to include prescription drugs, when enrolling after Jan. 1st 2006, encouraging Medicare recipients to participate in the new Part D Prescription Drug Plans. In lieu of selecting two separate plans, most anyone already on Medicare Parts A and B living in our fine state can choose to take *advantage* of a dramatically lower-cost Medicare Advantage Plan. Medicare Advantage Plans offer comprehensive benefits that Medicare *and* a supplement would cover, plus RX coverage in a single package.

These plans open the door to those who cannot otherwise become approved for traditional supplements due to pre-existing health conditions. It goes without saying that anyone on a tight budget or someone who just plain wants to watch their budget would be remiss not to investigate Medicare Advantage Plans.

Medicare Advantage Plans provide lower overall health care costs and substantial savings for beneficiaries through comprehensive benefits and coordinated care including reduced prescription drug costs, all in a single health plan. Currently, seven private insurers in New Mexico, all appointed by the Center for Medicare and Medicaid (CMS), offer different style plans including PPO, HMO, and Fee-For-Service. There are many benefits and fee variables among these plans in which to be aware.

The numbers to look for in comparing these plans would be *premium, deductible, co-pay, out of pocket, and in-network /out-of-network* rates. Since these concepts seem foreign to the lay person, it's best to speak with an insurance representative who is certified by Medicare to sell this product, and can explain how their plan directly relates to individual needs.

Provider Networks and Formularies can also range widely among companies. It's important to find out if your physicians and drugs are included in the plan you are choosing. Each company has a Summary of Benefits Booklet which outlines each and every service. Call Medicare direct: 800-633-4227 to determine which companies offer Medicare Advantage Plans in your area, or call your local Medicare insurance representative.

Terri Tobey, Medicare Sales Specialist
Blue Cross Blue Shield New Mexico

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki— I just received a copy of my bone density report. It says I have osteopenia. My doctor told me not to worry about it, but I don't want to end up stooped over like my mother. What is the treatment for osteopenia? Gloria B. Rio Rancho, NM.

Dear Gloria— You bring up a question that is often asked by doctors themselves, and one that does not have a simple answer. In fact, since “osteopenia” is not a disease and does not have one treatment, there really is no answer to your question. Instead of trying to answer an unanswerable question, I will ask, and try to answer, some other related questions.

What is osteopenia? This is a word that is used to describe a range of bone density between normal and osteoporosis. Bone density is reported as a “T-score.” When the T-score is -1.0 or higher, it is called normal, and when it is -2.5 and below, it is called osteoporosis. Most people with a normal T-score do not need to receive drug therapy, and most people with

osteoporosis can benefit from drug therapy. Between -1.0 and -2.5 is a gray zone called osteopenia. It is a wide range of bone density that covers a wide range of fracture risk. Some patients with osteopenia should be treated with drugs, and others should not.

Now that I have you really confused, I will go on to the next question. Which patients with osteopenia should be treated with drugs? To decide this, we need to estimate the risk of fracture by considering “clinical risk factors” for fracture. These include family history of fracture, personal history of fracture, low body weight, cigarette smoking, and taking drugs that can harm the skeleton, such as steroids. If you have osteopenia and enough of these risk factors, then drug treatment may help to reduce the risk of fracture.

If osteopenia is not treated with drugs, then nothing is done? No, of course not. All of us need to take care to exercise regularly, get enough calcium and vitamin D, avoid smoking and excess alcohol.

Sincerely,
Mike Lewiecki

**DIAGNOSIS AND RISK:
WHAT IS THE DIFFERENCE?**

The question that you see to the left brings up some interesting points about the process physicians use in making decisions about patient care. The World Health Organization has established some guidelines that doctors use for diagnostic classification of bone density. We label a patient as being in one of three categories depending on the T-score— normal, osteopenia, or osteoporosis. This is very convenient for discussing problems and billing insurance companies, but greatly oversimplifies the situation.

What we really care about is the strength of bones and the likelihood that they will break when normal bones would not. Bone density is one of many factors that determine the risk of fracture. Although a patient with a T-score of -2.4 has osteopenia and one with a T-score of -2.5 has osteoporosis, the fracture risk is really about the same if all other factors are equal. A doctor must consider all risk factors for fracture in order to make the best possible decision about using drugs for treatment.



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.