

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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Are you really taking your medicine?



There is a hot topic in the medical world called “adherence to therapy.” This is a general term that refers to patients filling prescriptions they are given, starting to take the medication, continuing to take it, and taking it correctly. Although most doctors like to believe that patients follow their advice and take medications they prescribe, studies show that this is often not the case.

It is common for patients to not take medications for serious diseases, such as diabetes and congestive heart failure. It is even more common to not take medications for chronic diseases that cause no symptoms, such as hypertension, high cholesterol, and osteoporosis. The main consequence of hypertension is stroke. For high cholesterol it is heart attack. And for osteoporosis it is fracture— bones breaking under circumstances where they would not normally break. Medications have been proven to be effective at controlling these problems and reducing the

risk of their consequences. However, most research studies have shown that only about one-half or less of patients prescribed medication for osteoporosis are still taking the medicine a year later!

Why is it that so many of us do not take medications which can help us to live longer and more productive lives? There are many reasons. Sometimes we don’t believe what the doctor tells us. Other times we believe but don’t care. Medication can be expensive and have side effects. We may just get too busy and forget. And taking medication may be a nuisance.

With osteoporosis drugs, help is on the way. A new pill is now available that is only taken once a month. Soon an injection that is given once every 3 months may be approved, and research is underway to test injectable drugs given once every 6 or 12 months. Ask your doctor 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, 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.

Postmenopausal Osteoporosis Treatment & Prevention

This is a 1-year study for postmenopausal women with osteoporosis or low bone mass to compare two approved medications, monthly oral ibandronate with once weekly alendronate.

You may qualify for this study if you are:

- A woman, age 55 to 84 at least five years postmenopausal
- Able to walk
- Low Bone Density of the spine and hip
- Able and willing to comply with the protocol for its duration.

2262

Once A Year Treatment For The Prevention Of Bone Loss In Postmenopausal Women With Osteopenia

You may be eligible to participate in a 2-year clinical research study designed to evaluate the efficacy and safety of a new investigational drug for the prevention of bone loss in postmenopausal women with Osteopenia. Compensation is available to qualified participants.

You may qualify for this study if you are:

- A female, at least 45 years of age, and

- Naturally or surgically postmenopausal, and
- Generally in good health, and
- Must not have been on hormone replacement therapy for the last six months, and
- Meet all other entry criteria.

2254

Restless Legs Syndrome

We are looking for men and women to participate in a 12 week study testing an investigational treatment of Restless Legs Syndrome (RLS) using a marketed drug.

You may qualify for this trial if you meet all study entry criteria:

- Men and Women who are between the age of 18 to 79

- Females should be non-child bearing potential (i.e., physiologically incapable of becoming pregnant, including any female who is postmenopausal)
- Must experience sleep disturbance when RLS symptoms are present
- Usually experience onset of RLS symptom no earlier than 5PM and prior to bedtime.

2258

Osteoporosis In Men

We are looking for men to participate in a 2 year clinical research study testing an investigational treatment for osteoporosis.

You may qualify for this clinical research study if you:

- Are age 25 to 85
- Have a low bone mineral density and diagnosis of osteoporosis
- Do not have any major exclusionary medical conditions
- You have not had therapies such as treatment with bisphosphonates in the last 2 years,

- Prior use of PTH for more than one week
 - Any prior use of strontium, ranelate or sodium fluoride
 - Use of systemic corticosteroids in the last year,
 - Prior exposure to anabolic steroids. (abbreviated list)
 - You are willing to attend scheduled study visits and procedures per protocol
- Reimbursement for time and travel is available to qualified participants. 2263

Postmenopausal Osteoporosis

This is an open label, 12 month research study of the effect of an investigational medicine in postmenopausal women with osteoporosis treated previously with risendronate or alendronate. Reimbursement for time and travel is available to qualified participants.

You may qualify for this study if you are a:

- Woman, at least 10 years post

menopausal (natural)

- Have been using resendronate or alendronate (daily or weekly) uninterrupted for a minimum of 24 months
- Must be able to self-inject or have a person to perform daily injections
- Take at least 1000 mg of calcium (from all sources)
- Generally in good health

2249

Treatment of Chronic Low Back Pain

This is a 1-year study to evaluate the safety of bicifadine in patients with moderate to severe chronic low back pain.

You may qualify for this study if you are:

- Male or female, ages 18-65
- Women must be postmenopausal, surgically sterile or

using birth control

- Able to walk
- Requires an average, daily analgesics for the treatment of low back pain over the past 3-months.

2261

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



July 14, 2005
Dr. Margaret Royson
Topic to be determined

August 11, 2005
Dr. Lance Rudolph
"Diagnosing Osteoporosis in Patients with Disabilities"

September 8, 2005
Dr. Elliot Pierce
"Osteoporosis Non-Pharmaceutical & Pharmaceutical Treatment"



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

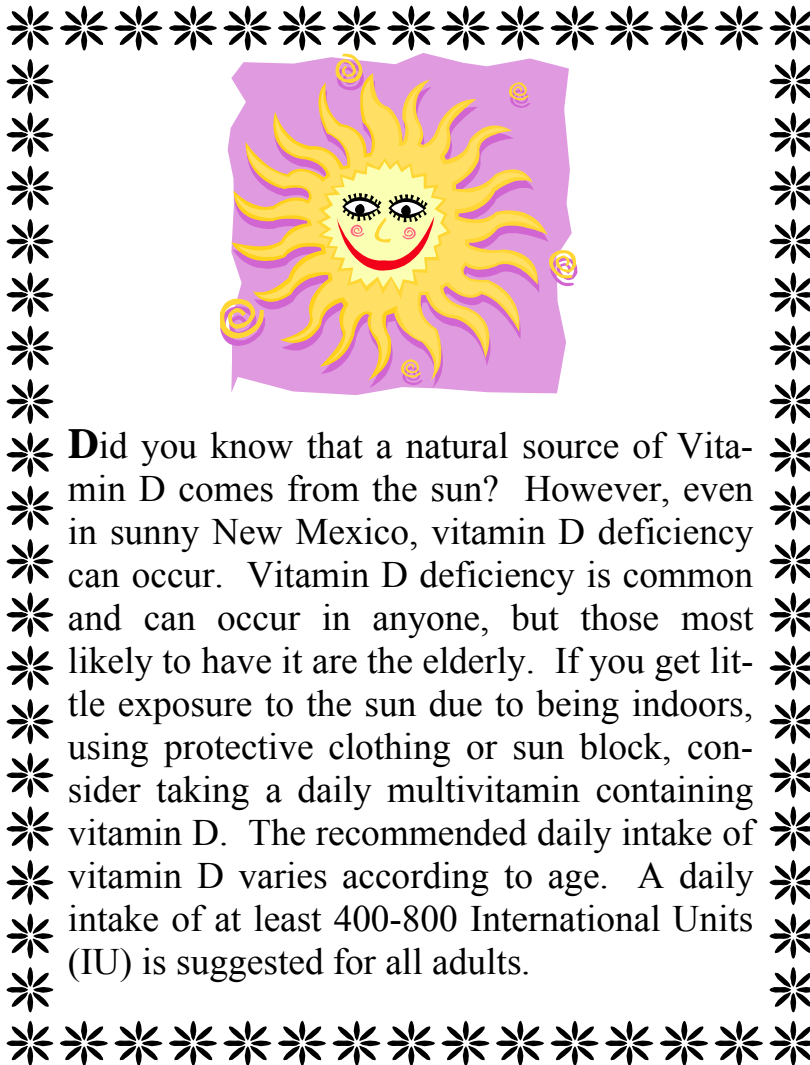
Are you a postmenopausal woman with osteoporosis or osteopenia?

This 12 month study is for postmenopausal women with Osteoporosis or Osteopenia, previously treated with daily/weekly Fosamax® or Actonel® and not tolerating the GI side effects of the medication (e.g., dyspepsia, abdominal pain, nausea, and diarrhea).

You may qualify for this study if you meet all study entry criteria

- Have discontinued daily/weekly Fosamax® or Actonel® therapy because of GI intolerance
- Have discontinued previous osteoporosis medication for at least 3 months
- Are able to stand or sit in the upright position for 60 minutes
- History of major, upper GI disease or active ulcer
- Generally in good health

2260



Woman to Woman
By

Julia Chavez, CNP

ABOUT YOUR BLADDER

Bladder control problems affect more than 200 million people in the world. Approximately 13 million Americans have urinary incontinence. This means loss of control of urine with a sudden movement or pressure (coughing, sneezing, laughing, or jumping). Overactive bladder (OAB) is a problem which includes urinary urgency or incontinence.

OAB is more common among the elderly and can affect both men and women. There are factors that are common in older adults such as diabetes, heart failure, and multiple medications that can contribute to urinary problems. OAB and incontinence tend to be underreported and under-diagnosed due to misinformation and embarrassment. Urinary frequency and having to get up at night to urinate and rushing to the bathroom to avoid accidents can increase the risk of falling, resulting in fractures.

Treatments vary from behavioral changes such as pelvic floor exercises, dietary changes, restricting intake of alcohol or caffeinated beverages, to medications that are available from your provider, or in rare cases surgery. If you have questions or problems with bladder control, talk to your doctor or nurse practitioner.

On The Light Side

SISTERS AND BROTHERS

SISTERS - Three sisters ages 92, 94 and 96 live in a house together. One night the 96 year old draws a bath. She puts her foot in and pauses. She yells to the other sisters, "Was I getting in or out of the bath?" The 94 year old yells back, "I don't know. I'll come up and see." She starts up the stairs and pauses "Was I going up the stairs or down?" The 92 year old is sitting at the kitchen table having tea listening to her sisters. She shakes her head and says, "I sure hope I never get that forgetful." She knocks on wood for good measure. She then yells, "I'll come up and help both of you as soon as I see who's at the door."

BROTHERS - "I CAN HEAR JUST FINE!" Three retired brothers, each with a hearing loss were playing golf one fine March day. One remarked to the other, "Windy, isn't it?" "No," the second man replied, "It's Thursday." And the third man chimed in, "So am I. Let's have a beer."



THE OSTEOPOROSIS FASHION CHALLENGE

The physical changes that may occur with osteoporosis can create fashion challenges. For example:

- Forward projection of the shoulders and head causes the back of the neckline to gape and the front of the neckline to sit close to the base of the throat.
- Rounding of the shoulders causes the garment to pull across the shoulders
- A protruding abdomen causes the front waistband to sit too high above the waist and the hem line to rise in front.
- Height loss causes skirts and pants to be too long.

Your goal should be to create the appearance of a STRAIGHT LINE from head to toe and to direct the eye away from an deformity

How do you disguise rounded shoulder and a curved back (dowager's hump)?

Consider:

Scarves and jewelry
Shoulder pads
Stylish hats
A-line styles

Avoid:

Epaulets
Set-in sleeves
High turtlenecks
Mandarin collars

How do you disguise a protruding abdomen?

Consider:

A-lines styles
Tunics
Solid colors
Loose jackets that conceal the tummy

Avoid:

Tight-fitting belts
Fitted waistlines
Close-fitting jackets
Tight-fitted straight skirts

Take a look at your existing wardrobe to:

- 1 - determine what you already own that works,
- 2 - identify what will work if modified, and

Ask Dr. Mike Lewiecki about OSTEOPOROSIS

Dear Dr. Lewiecki– I have a hard time taking any of the medications I have tried for my osteoporosis. Some give me heartburn and indigestion. One gave me leg cramps. I even tried a spray in my nose, but got nose bleeding from it. My doctor is about ready to give up on me. I am afraid I will end up being stooped over like my grandmother. What can I do? Victoria B. Silver City, NM.

Dear Victoria – Your situation is one that I commonly see. Do not give up. There is hope.

First of all, if it has not been done recently, a bone density test should be done at an experienced osteoporosis center to find out how bad (or good) your bones are. Then, a few simple blood and urine tests can determine whether there are any contributing diseases or other factors that might effect your bone density, your response to therapy, or cause side-effects from treatment.

Finally, once all of that has been done, your treatment options can be considered. The basis for any

treatment is getting an adequate daily intake of calcium and vitamin D. Regular weight-bearing exercise, such as walking, is important to improve your leg strength and balance, which may make you less likely to fall and break a bone. Tai-chi, yoga, and physical therapy can also do a lot to help with balance. Avoidance of cigarette and moderation in alcohol intake is helpful.

As for medications, there are some that are inexpensive and easy to take for certain situations. For example, some diuretics (water pills), normally used for problems with blood pressure or swelling, can help if there is excess calcium in the urine. If your tests show a problem with intestinal absorption, such as celiac disease, a change in diet can help tremendously. Finally, there are new drugs available that are giving much less frequently or by injection that may work for you. Read the accompanying articles in this newsletter, and keep in touch with your doctor for new developments.

Sincerely,

Mike Lewiecki

LONG DOSING INTERVALS FOR OSTEOPOROSIS MEDICATIONS

There is a trend with osteoporosis therapy toward longer and longer intervals between dosing. We started with a pill once a day. Next we had a once a week pill. Now there is a monthly pill. Research is being done on injections given once every 3 months, once every 6 months, and even once a year.

Surprised? How can a single shot work for a whole year? And if there is an allergic reaction or a side effect, does that mean it will last a whole year? These are all good questions, and ones that many doctors have asked as well. For the once a year shot, think of your bones as the ultimate time release capsule. The medicine has such an extremely strong attraction for your bones that it stays there for many years and continues to work long after the shot was given. Fortunately, side effects have been few and mostly very mild. If there are side effects, they usually last only a few hours or a few days after the shot is given.



Support osteoporosis education in New Mexico. 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, or visit the web site at www.osteoporosisfoundationnm.org.