

# 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

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## Why Volunteer for a Clinical Research Trial?

Part II of a II Part Series

### How Will Your Trial be Safeguarded?

Clinical trials are federally regulated with safeguards to protect the participant. The trials follow a carefully controlled protocol, which details the study plan. The protocol describes a participant's required profile, medical procedures involved, medications, dosages and duration of the study. Participants are seen regularly by the research staff to monitor their health and determine the safety and effectiveness of the treatment.

### How is a Participant Chosen for a Study?

All clinical trials have guidelines allowing or disallowing a participant to qualify for a study. The criteria are based on age, gender, type of disease, previous treatment history, existing medical conditions and any medications currently being taken. It is important to note that the inclusion and exclusion criteria are not used to reject people personally. Instead, the

guidelines are used to identify appropriate participants, ensure safety during the trial, and provide the researchers accurate data to answer the question they plan to study.

### Are There Risks in a Clinical Trial?

There are risks involved in participating in clinical trials. The experimental treatment may not be effective for the participant. Serious or even life threatening side effects could occur. Side effects are any undesired action or effects of the experimental drug. The risks and potential benefits are explained in a consent form, a document detailing the facts about the trial. Our research staff will explain the specific details of each trial. The participant must read and decide whether or not to be part of the study. The consent form is not a contract and the participant may withdraw from the trial at any time.



### 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](http://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 [ydbusuelas@nmbonecare.com](mailto:ydbusuelas@nmbonecare.com).

### 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*

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Drug Study Coordinator*

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*Drug Study Coordinator*

**Michele Dingman, BA, CCRC**

*Drug Study Coordinator*

**Aspen Montoya, CCRC**

*Drug Study Coordinator*

**Princess Dougan, MD, CRC**

*Drug Study Coordinator*

**Karen Strickler, BS, CRC**

*Drug Study Coordinator*

**Nanette Nguyen**

*Research Medical Assistant*

**Isabel Torres, RT(R), CDT**

*Bone Densitometry Technologist*

**Ginnie Laroi-McClure, RT(R), CDT**

*Drug Study Recruiter*

**Vicky Morris-Dueer, BA, MA**

*Drug Study Recruiter*

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*Medical Assistant*

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*Medical Assistant*

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*Billing/Bookkeeping Supervisor*

**Kim Fletcher**

*Billing Specialist*

**Stacey Escudero**

*Medical Secretary*

**Joe Ann Chavez**

*Medical Secretary*

## 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.*

### Birth Control

This is a 12-month research study evaluating an investigational birth control pill. Subjects will receive either the investigational birth control pill or an approved birth control pill.

**You may qualify for this study if:**

- You are a sexually active female between the ages of 18 and 50
- Are willing to use a birth control pill for 12 months
- In general good physical and mental health

2291

### High Cholesterol

This is a 5 month research study evaluating an investigational Drug for high cholesterol. This is a randomized clinical Research Study. The participants will receive either the investigational drug, or an approved treatment

**You may qualify for this study if:**

- you suffer from high cholesterol
- are between the ages of 18 and 80

2290

### Senior Hypertension

This is a 36-week, randomized, double-blind, parallel group, active-controlled, optional titration study comparing an aliskirin-based regimen to a ramipril based regimen in patients over the age of 65 with systolic essential hypertension.

**You may be eligible to participate in this study if:**

- You are over the age of 65
- Have been diagnosed with hypertension

2289

### 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
- 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

**Functional Dyspepsia**

This is a 16-week clinical research study to assess the effect of a medication versus placebo in the treatment of functional (non-ulcer) dyspepsia.

**You may be eligible to participate if you are:**

- Are 18-75 years of age

- Have pain and/or discomfort in your upper abdomen for at least one week for the past month
- Have a documented history of functional dyspepsia
- Able and willing to comply with the study for its duration

2281

**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

2271/85

**Irritable Bowel Syndrome**

This is a an 8-week study to evaluate the safety and efficacy of an investigational medication compared with an FDA approved drug versus placebo for the relief of abdominal pain or discomfort in patients with IBS

**You may qualify for this study if you are:**

- At least 18 years of age and diagnosed with IBS
- Recurrent abdominal pain or discomfort occurring for the first time at least six months ago
- Able and willing to comply with the study for its duration.

2286

**Type 2 Diabetes**

This study is being undertaken to compare the effect of inhaled insulin in combination with basal insulin therapy versus a premix of intermediate acting and rapid acting insulin.

**You may qualify for this study if you:**

- Have been diagnosed with diabetes for at least two years
- Are currently receiving a pre-/self mixed insulin therapy 2-3 times daily
- Non-smoker between the ages of 18 and 80

2280

**Osteoporosis Foundation of New Mexico**

**Free Educational Presentations**

2nd Thursday of every month:  
Rehabilitation Hospital of New Mexico  
(formerly St. Joseph's Rehabilitation Hospital)  
505 Elm St NE  
Albuquerque, NM 87102  
1:30 - 3:00PM

October 12, 2006



Terri Toby  
Blue Cross Blue Shield  
New Mexico  
"Medicare Supplemental Options"

November 9, 2006

Janette Wiggins  
"Osteoporosis Overview-Treatment, Medications, and Insurance"

December 14, 2006

Annette Torres, CDT  
"Bone Density Testing-What to Expect"

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

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## **On the light side**

A man feared his wife was not hearing as well as she used to, and he thought she might need a hearing aid. Not quite sure how to approach her, he called the family doctor to discuss the problem.

The doctor told him there is a simple informal test the husband could perform to give the doctor a better idea about her hearing loss.

"Here's what you do," said the doctor. "Stand about 40 feet away from her and in a normal conversational speaking tone, see if she hears you. "

"If not, go to 30 feet, then 20 feet, and so on until you get a response."

That evening, the wife is in the kitchen cooking dinner and he was in the den. He said to himself, "I'm about 40 feet away. Let's see what happens."

In a normal tone he asks, "Honey, what's for dinner?" No response.

So the husband moves to closer to the kitchen, about 30 feet from his wife, and repeats, "Honey, what's for dinner?" Still no response.

Next he moves into the dining room where he is about 20 feet from his wife and asks, "Honey, what's for dinner?" Again, no response..

So, he walks up to the kitchen door, about 10 feet away. "Honey, what's for dinner?" Again, there is no response.

So he walks right up behind her. "Honey, what's for dinner?"  
(I just love this.)

"Earl, for the 5th time, CHICKEN!"



## **NEWS FLASH**

### **Flu Season is Right Around the Corner**

One night, as he finished his last beer, Joe's doorbell rang. He answered the door and found a six-foot cockroach standing there. The bug grabbed him by the collar and threw him across the room, then left. (Maybe a Texas cockroach?)

The next night, the doorbell rang and he found the same six-foot cockroach standing there. The big bug punched him in the stomach, then left. The same thing happened the next night. This time, he was kneed in the groin and hit behind the ear as he doubled over in pain. Then the big bug left.

The following day, Joe went to see his doctor. He explained the events of the preceding four nights. "What can I do?" he pleaded. "Not much," the doctor replied. "There's just a nasty bug going around."

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



## **ALLERGIES**

Allergic rhinitis is caused by the body's immune system reacting to some type of environmental trigger. The most common triggers are dust, mold, pollen, trees, grasses and animals. This year seems to be filled with triggers. Symptoms include sneezing, runny nose, stuffiness and itchy, watery eyes.

Sometimes it is difficult to distinguish allergies from viral upper respiratory infections. Allergies will never cause fevers. The diagnosis can be based on a history of symptoms and there is frequently a family history of allergies. More detailed information can be obtained from blood tests or skin testing.

These tests would be done at an allergist's office. Avoiding substances that trigger allergies can prevent symptoms, but is not often possible. Nasal corticosteroid sprays decrease the nasal inflammation and are relatively safe for long-term use. They help prevent allergic reactions, therefore prevent symptoms. Antihistamines dry the mucous membranes but can also cause sleepiness and other problems, especially in older people.

The newer ones require a prescription, but do not have the side-effect of drowsiness. There are a couple of over-the-counter, non-drowsy antihistamines available. Allergy shots can help build long-term tolerance, but can take months or years. We no longer use kenalog shots for allergies as they may have more side-effects than we want, including higher risk for developing osteoporosis. Antibiotics do not help allergies.

If you are having trouble differentiating between allergies and viral upper respiratory infections, see your primary care provider.



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

**Dear Dr. Lewiecki– I recently got a severe pain in the lower back when I tried to open a bedroom window that was stuck. My doctor ordered an X-ray that showed fracture in my spine. The pain is now getting better, but it is still not gone after 2 months. I am 67 years old and feel fine except for my back pain. What should I do now? Priscilla T. Santa Rosa, NM.**

Dear Priscilla– Vertebral (spine) fractures are the most common type of fracture due to osteoporosis. You are very likely to have osteoporosis, although tests should be done to be sure that there is no other cause of weak bones. This is how I usually handle situations such as yours:

1. A bone density test provides helpful information about the status of your bones and serve as a baseline for comparison to monitor the effects of treatment.
2. Laboratory tests to measure things such as your blood calcium level, vitamin D level, protein levels, kidney

function and thyroid status can assist in finding out if any other important medical disorders are present. If a problem is found, then it must be addressed. Vitamin D deficiency, for example, is very common and may contribute to weak bones.

3. Usually a vertebral fracture heals after about 6 weeks. An MRI scan of the spine should be considered if pain goes much longer than that. This can help determine how old the fracture is and whether any unusual bone disease is present.
4. Anyone with a past fracture with minimal trauma, such as you, is at very high risk for future fracture. Assuming that you lab tests show serious problems, then it may be worthwhile to take medication to strengthen your bones and reduce the risk of future fractures. Many medications are now available, and most of them can reduce the risk of fractures by about 50%.

I suggest you talk to your doctor about further testing and possible treatment.

Sincerely,  
*Mike Lewiecki*

**WHEN BACK PAIN DOESN'T GO AWAY– WHAT NEXT?**

There are many reasons for back pain to persist longer than we would like, as described in the letter on this page. Sometimes it is due to a muscle strain, arthritis or herniated disc. Rarely, it is caused by more serious problems, such as cancer or infection in the bone. Vertebral fractures, which are easy to detect with an simple X-ray or spine image taken with a bone density instrument, are the most common type of fracture in patients with osteoporosis. Usually pain caused by these fractures resolves after about 6 weeks. If pain continues beyond this time, especially if it is severe, then further evaluation should be done.

Non-invasive procedures called vertebroplasty and Kyphoplasty are one way to treat chronic vertebral fracture pain. A small amount of “bone cement” is injected directly into the bone that is fractured. Over 90% of patients experience pain relief within hours of having this done. Not everyone with a fracture needs this done, but for those who do, it offers great relief of disabling symptoms.



**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.**