My Experience in Research
Voices from Volunteers

I am currently in a clinical trial for an Amgen treatment for osteoporosis. This is the third clinical trial in which I have participated during the last seven years, and I have found my participation to be rewarding for several reasons.

First, it gives me the chance to try a new medication when I have run out of viable options. In a previous trial for arthritis treatment, the drug I received is now my medication of choice.

Second, I feel that I am contributing valuable information for the development of new pharmaceuticals and for genetic research. This gives me good feelings!

Third, the regular tests and exams I get are certainly worthwhile. Even though the results are blinded, I'm sure that if anything was found to be out of line I'd hear about it!

Fourth, I have been able to pass on information I have gained to friends and relatives who suffer from the same conditions that afflict me.

I would certainly consider participating in more trials that are relevant to my health.

My experience at the New Mexico Clinical Research and Osteoporosis Center has been most enjoyable. All the staff members I have met are very pleasant and really seem to care about my well being.

Janet D. Trauth
March 5, 2007

I have been in a study with Dr. Lewiecki for 3-1/2 years. I have enjoyed meeting all of the staff and becoming more educated about osteoporosis. If I ever had any questions regarding the study or how I felt about any tests, I was fully satisfied with the explanation from a study coordinator or doctor.

I have had very little discomfort from the IV infusions of study medication and the bone biopsy I had done at the end of the first 3-year study. I do hope this study is successful, this would mean it could benefit many in the future.

The benefits are a decreased rate of bone loss, which may also reduce fractures.

I have told many of my friends about the study and the possible benefits that may result for all participants. I recommend that all participants continue with the study. I encourage anyone that qualifies to join a study group.

Margaret Cole
March 20, 2007

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.

Do You Have the Flu?

This is a one month research study to assess the outcomes of patients presenting within 48 hours of developing flu symptoms.

You may qualify for this study if you are:
- Over the age of 18
- Have flu symptoms for no more than 48 hours

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

Osteoarthritis

This is a 59-week, open label, long term safety study of an investigational treatment for moderate to moderately severe pain associated with osteoarthritis.

You may qualify for this study if:
- You suffer from osteoarthritis in at least one joint
- Are between the ages of 45 and 80

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 and have been diagnosed with hypertension

Gout

This is a 6-7 month research study to see if an investigational drug can lower uric acid levels in the body (high uric acid can cause gout). If you have a history of gout or are currently experiencing gout symptoms, you may qualify to participate.

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.
**Irritable Bowel Syndrome**

This is a 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

**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

**Treatment of Postmenopausal Hot Flashes**

A 26-week research study in healthy postmenopausal women suffering from vasomotor symptoms (Hot Flashes).

**You may qualify for this study if you are:**
- Postmenopausal female
- Suffer from at least 7 hot flashes in a 24 hour period.

**Male Osteoporosis**

This is a one year clinical research study testing ibandronate for treatment of osteoporosis in men.

**You may qualify for this study if you are:**
- A male between 30 and 79
- Have a diagnosis of osteoporosis

**Severe Osteoporosis**

This is a one-year clinical research trial testing an investigational treatment for severe osteoporosis in postmenopausal women.

**You may be eligible to participate if you are:**
- A post-menopausal female between 45-89 years of age
- Have been diagnosed with severe osteoporosis

**Osteopenia**

New Mexico Clinical Research & Osteoporosis Center is conducting a research study using an investigational Vitamin D compound for the treatment of low bone density.

**You may be eligible to participate if you are:**
- If you are a postmenopausal woman between the ages of 55 and 80

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

Tips To Encourage People To Start Exercising

I. Preparing for Physical Activity:
   - Choose something you’ve enjoyed in the past or have wanted to do.
   - Know yourself – can you stick with a plan of home activity, or are you better in a group or public setting?
   - Make a plan and follow it, but be flexible and keep your long-term goals in mind.
   - Plan how you’ll reward yourself for your efforts (preferably not food).
   - Keep track of your progress – it doesn’t matter how, just so it is meaningful to you.

II. General:
   - Start out slowly; adjust your activity so you feel challenged but not exhausted.
   - The U.S. Surgeon General’s recommendation for health is 30 to 60 minutes of moderate activity on most days of the week.

III. Easy Ways to Add More Activity:

At Home
   - Go out for a short walk whenever you have a few minutes—just add up.
   - Walk or bike to errands.
   - When walking, pick up the pace from leisurely to brisk.
   - Pedal a stationary bicycle, stretch or do short bouts of activity while watching TV.
   - Walk a dog or play actively with the kids.
   - Park farther away at the shopping mall and walk the extra distance.
   - Walk extra laps around the mall or grocery store; check out mall walking programs.
   - Housework and gardening count towards your daily activity!

At the Office
   - Take the stairs instead of the elevator.
   - Stand or pace while talking on the telephone.
   - Walk down the hall to speak with someone rather than using the telephone.
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Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS

Dear Dr. Lewiecki– When I married my wife, I was a few inches taller than she. I think we have both shrunk as we have gotten older, but now we are the same height and my posture is not as good as it used to be. She says I could have osteoporosis, but I told her that men don’t get osteoporosis. We bet dinner at our favorite restaurant on this. Who gets to pay the bill? John T., Albuquerque, NM.

Dear John– Sorry, my friend. Get out that credit card, because you will need to pay up. Although women are more likely than men to get osteoporosis, men get it too. There are about 44 million Americans with osteoporosis or low bone mass that can lead to fractures, and 20% of those are men. That adds up to almost 9 million men at risk for fractures. You could be one of them.

The most common fracture with osteoporosis is in the spine. These fractures can sometimes cause severe back pain and require immediate medical attention; however, more often than not, there is little or no back pain, and a physician is never seen. Spine fractures can eventually cause loss of height and a stooped posture. When height has gone down by more than 1.5 inches, we usually like to get an image of the spine by standard X-ray or with the DXA machine that is used to measure bone density. If fractures are seen, then other tests, including measurement of bone density, should be done.

Men with osteoporosis often have an underlying problem that is causing it (See column to the right). A thorough medical evaluation should be done, and any problems that are found should be addressed. Fortunately, there are now good medications for treating osteoporosis in men, just as there are for women.

For you, I suggest a visit to your doctor to talk about you bones. A few simple tests can show whether you have osteoporosis or something else. If you do have osteoporosis, there a safe and effective medications you can take to make your bones stronger and reduce the risk of future fractures.

Sincerely,

Mike Lewiecki

MEN AND BONES

How does a man know if he has osteoporosis? The same way as a woman– with a bone density test. This is a simple painless test that is now recommended for all men age 70 and older. It is commonly done for women after the time of menopause, and should be done for many men as well. If this gives a low reading with a “T-score” of –2.5 or less, then a diagnosis of osteoporosis can be made.

A bone density test is a good idea for any man over the age of 50 who has broken a bone without severe trauma, such as falling from the standing position or doing some light lifting. Also, men with low testosterone levels and those taking certain medications (prednisone, seizure medications, drugs for prostate cancer) should consider having a bone density test.

Men with fractures often do even worse than women. A man with a hip fracture, for example, has a higher risk of dying or being disabled than an woman.

If you want to know more about osteoporosis in men, talk to your doctor.

To participate in clinical research studies, call (505) 923-3232.