CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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Why should you participate in research?

As a volunteer in a clinical research trial you will not only take on an active role in your own health care but you are participating in the development of medical therapies that may offer better treatments and cures for diseases. Gaining access to new research treatments before they become publicly available in the marketplace could provide you with medical treatment that is t currently not available, ultimately improving the medical care you now receive.

Janet T, a current research patient discovered this for herself. "I am currently in a clinical trial for treatment for osteoporosis. This is the third clinical trial in which I have participated during the last ten 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 development the of new pharmaceuticals for genetic and This gives me good research. 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!"

My experience at the New Mexico Clinical Research & 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." she reported.

All clinical trials have guidelines allowing or disallowing a participant

to qualify for a study. The criteria are based on medical history and current treatments. 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, to be certain that people are not unnecessarily put at risk.

New Mexico Clinical Research & Osteoporosis Center conducts trials for pharmaceutical companies. These clinical trials are done to confirm effectiveness, monitor side effects, make comparisons to commonly used treatments, and collect information on the safety of drugs and treatments under study. Our dedicated clinical team of doctors and research professionals monitor participants carefully during the trial and remain in contact with them after completion.

We conduct clinical trials for many different indications, including, osteoporosis, hypertension (high blood pressure), gout, arthritis, diabetes, GERD (heartburn), IBS and others. If you are interested in participating call a study specialist at **923-3232** for more information.

Whatever reason you choose to participate in clinical research, be assured that you are engaging in the advancement of medical treatments, therapies, and cures for chronic or lifethreatening diseases.



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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, 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. If there is nothing for you now, there may be next time.

IBS with Constipation

This is a randomized, placebo controlled study of an investigational medication to relieve the symptoms of Irritable Bowel Syndrome that is constipation predominant. You may qualify for this study if you are:

- Over the age of 18
- Have less than 3 bowel movements per week for at least the past month
- Have pain associated with your symptoms. *Forrest Lin-MD/31*

Gout

- This is a randomized placebo controlled study of an investigational medication to lower uric acid which causes gout flares. You may be eligible to participate if you are:
- Over the age of 18
- Diagnosed with gout

BCX

High Blood Pressure

This is a randomized study of an investigational medication in combination with an approved medication for the treatment of hypertension. You may qualify for this study if you are:

- Over the ages of 18
- Have high blood pressure treated with less than 3 medications *Takeda 491*

Heartburn

This is a randomized, placebo controlled study of an investigational medication for Heartburn or Gerd. You may qualify for this study if you are:

- Take heartburn medication such as Prevacid or Nexium twice a day
- Have less than 1 episode of heartburn a week on your current medications.

Takeda 178

Gout Prevention

A six-month study to assess the prevention of gout flares when starting allopurinol or other urate lowering therapy. You may be eligible to participate if you are:

- Over the age of 18
- Are willing to start daily medication to prevent flares.

Regeneron 815

Nocturia

A 12 week study to assess the safety and efficacy of an investigational inhaled medication for the treatment of frequent night time waking to urinate. You may be eligible to participate if you are:

- Between the ages of 50 and 80 and
- Have more than 2 episodes a night, at least 5 nights a week, for the past 6 months

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Diabetes

A 3 and half year study of an investigational medication given once weekly to help control diabetes. You may be eligible to participate if you are:

- Have type 2 Diabetes and are currently taking Metformin plus one additional medication for the past 3 months
- Are not currently well controlled.

GSK Harmony

Osteoporosis

A clinical trial to assess the safety and efficacy of an investigational medication compared to already approved medications. You may be eligible to participate if you:

- Are a postmenopausal woman between 55 and 85
- Have osteoporosis
- Have not been treated with IV bone medications and have not taken oral bone medications in the past year.

Osteoporosis

A 48-week research study of oral calcitonin vs. inhaled calcitonin in postmenopausal women with osteoporosis. You may be eligible to participate if you:

- Are a postmenopausal woman over 45 years of age
- Have osteoporosis and currently not be taking any bone medications
- Not currently being treated with hormone replacement therapy. *Unigene*

Osteoporosis

This is a 12-month randomized research study to compare Forteo (a daily injection) with Reclast a once a year infusion and includes a bone biopsy procedure. You may be eligible to participate if you:

- Are a postmenopausal woman between 55 and 89
- Have osteoporosis
- Have not been treated with Forteo or Reclast and not taken any oral bone medication within the past 2 years.

Male Osteoporosis

A 24-month study to assess the safety and efficacy of an investigational drug in men with osteoporosis. You may be eligible to participate if you are:

- Between the ages of 30 and 80
- Have osteoporosis or are concerned you may have osteoporosis
- Are not currently being treated for osteoporosis

Amgen-Male

Resolution Revolution

This year will be different

Instead of making vague New Year's resolutions like getting fit, losing weight, or saving money, decide to do just one small positive thing every day.

Change doesn't happen overnight, but little changes every day could add up to a major overhaul by the end of the year. Pick simple, specific things that will help you progress towards a challenging but achievable goal, such as:

> Making the morning less stress full by getting up a half-hour earlier.

Eat a healthy breakfast. A high-fiber cereal such as oatmeal and some fruit, or an apple with string cheese. (cheese - a great source of calcium!)

Walk five minutes in one direction – a great weight bearing exercise.



Does someone you love have Osteoporosis?



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It's a fact! Many more men develop osteoporosis than prostate cancer. Osteoporosisrelated fractures, such as a broken hip, can have a devastating impact on a man's independence, mobility, and family life. And the serious risk for a man, whether he's 30, 50 or 60, is that he may not realize he's experiencing bone loss until it's too late to prevent brittle or broken bones.

New Mexico Clinical Research & Osteoporosis Center is currently enrolling men to help evaluate an investigational drug for osteoporosis. If you are between the ages of 30 and 85 and diagnosed with osteoporosis, lost more than an inch in height or have broken a bone, you may be eligible to participate.

Study participants receive study related mediations, medical care and evaluations at no cost and compensation may be available for those who participate.

Call Now! Don't Delay! 923-3232

New Mexico Clinical Research & Osteoporosis Center E. Michael Lewiecki, MD Lance A. Rudolph, MD

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



Woman To Woman By

Julia Chavez, CNP

WHAT IS IN YOUR GENES?

Are you aware that you could have inherited a risk for certain health conditions such as heart disease, diabetes, and certain cancers? Researching and knowing your family history can help you live a longer and healthier life.

It is important to collect as much information about your parents, grandparents, and siblings health history and share it with your healthcare provider. It is especially helpful to know about any close relatives who may have been diagnosed with cancer or heart disease before the age of forty. Armed with this information, you can help reduce your risks of developing the same problem with changes in diet and exercise and earlier screenings.

At New Mexico Clinical Research & Osteoporosis Center, we strive to obtain family medical history every year during your annual exam, but encourage you to inform us if you obtain any new information about your family genetics during the year.

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.

Osteoporosis Foundation of New Mexico

Educational Presentations

Manzano Mesa Multigenerational Center 501 Elizabeth SE Albuquerque, NM 87123 (505) 275-8731

> 1:30-3:00 PM <u>Quarterly:</u>

February 18, 2010 Leona Rubin, MA Topic: "My Active Life with Osteoporosis"

> May 13 2010 Joan Lewis, MD Topic: "Osteoporosis, the Silent Disease"

August 12, 2010 Jeff Rubin, chef/owner Savory Fare Topic: "Add Calcium, not Calories"

> November 12, 2009 To Be Determined

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want. There is limited space, so please sign up by calling 275-8731 in order to attend. A \$1 fee is collected in order to cover the cost of educational material.

Consider attending if:

- ✤ You have osteoporosis,
- You have a loved one with osteoporosis, or
- You are interested in learning more about osteoporosis.



Ask Dr. Mike Lewiecki about OSTEOPOROSIS

Dear Dr. Lewiecki– I know that exercise is good for osteoporosis, but I don't know where to start. I have seen different sorts of recommendations for what to do. I am afraid I will hurt myself it I don't do it right. Can you help me? *Victoria C., Albuquerque, NM.*

Dear Victoria- Physical fitness should be a goal for all of us, whether we have osteoporosis or not. It is easier to stay fit once you are there, but it is never too late to improve your level of fitness. Regular physical activity can give us more energy, reduce cholesterol blood and sugar, treat depression, and lower the risk of heart disease. Best of all, its free, if you want it to be, and you can do it at home.

You are not alone in wondering how to get started, since there is a great deal of conflicting advice in magazines, newspapers, TV, and the Internet. My first message to you is that almost anything you do is better than nothing, since being a couchpotato does not contribute to good health. Second, stay in vour comfort zone and use moderation. If something you do causes pain, is overly risky for your bones (parachuting, rock climbing?), or keeps you up at night worrying you will break a bone, then don't do it. Avoid bending over and lifting, since that puts a great deal of stress on your spine and could cause a fracture if your spine is very weak. Finally, keep active and enjoy yourself. If a physical activity is not enjoyable for you, you are not likely to stay with it, just as you are not likely to stick with a lifelong grapefruit diet, even if desperately want to lose weight.

Now, what specifically can you do? Walking is a great way to start. The more the better. It helps with leg muscle strength, improves balance, and reduces falls. Use light weights for upper body strength. Don't forget to exercise your back (see sidebar to the right). Ask your doctor for a prescription to see a physical therapist for customized advice. Go to the National Osteoporosis Foundation website at www.nof.org to order an exercise video. Consider yoga, Tai chi, or pilates. And don't forget- enjoy yourself.

Mike Lewiecki

BACK EXTENSION EXERCISES FOR OSTEOPOROSIS

The most common type of osteoporotic fracture is in the spine (vertebral fracture). Although these fractures may sometimes cause severe back pain and stooped posture, more often than not they cause no recognizable symptoms. You may simply have become shorter with age and have a mild backache, or perhaps have no backache at all. Nevertheless, it is important to know whether you have a vertebral fracture, because it may increase your risk of future fractures and change your treatment plan. A key component in the care of osteoporosis is exercise, with exercises of the back playing a particularly important role.

Back extension exercises can improve posture and enhance the quality of life in patients with osteoporosis. What is a back extension exercise? It's simple. Lie face down on top of a bed with a firm mattress, or on the floor, with a pillow under your abdomen. Then raise the upper part of your body and hold for 5 seconds. Rest for 10 seconds and do it again. Do 10 repetitions of this and take a breather. Do this every day, and do it more than once a day if you feel very energetic. You should feel the results within a few weeks. It should not be painful, so if you hurt, stop doing it until you feel comfortable starting again.



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.

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