

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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Why Volunteer for a Clinical Research Trial?

Part I of a II Part Series

New Mexico Clinical Research & Osteoporosis Center conducts pharmaceutical sponsored trials. Phase II trials evaluate the effectiveness and safety of experimental drugs or treatments involving large groups of people (100-300). Phase III trials study experimental drugs or treatments on larger groups of people (1,000-3,000). Both phases confirm effectiveness, monitor side effects, sometimes 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 if necessary, remain in contact with them after completion.

Should You Participate in a Clinical Research Trial?

As a volunteer in a clinical research trial you not only take on an active role in your own health care but are participating in the development of medical therapies that may offer better treat-

ments and cures for diseases. Gaining access to new research treatments before they become publicly available could provide you with medical treatment for that does not currently exist and may ultimately improve the medical care you receive.

Whatever reason you chose to participate in clinical research, be assured that you are engaging in the advancement of medical treatments for chronic or life-threatening diseases.

Are Clinical Research Trials Monitored?

Every clinical trial in the US must be approved and monitored by an Independent Review Board (IRB) to make sure the risks are minimal and are worth the potential benefits. An IRB is an independent committee of ethical physicians, statisticians, and community advocates whose prime endeavor is to safeguard and protect the rights of the participants.

We work closely with our IRB's to assure your safety and confidentiality

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 ydbrusuelas@nmbonecare.com.

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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.

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

Hypertension

This is a 12-19 day clinical research study to assess the effect of an investigational drug for sexual dysfunction on people with controlled hypertension. (You do not need to have a sexual dysfunction in order to participate.)

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

- Diagnosis of essential hypertension (stage 1 or 2), and on a stable regimen and doses of anti-hypertensive medications for a minimum of 2 months.

- Between 21 and 70 years of age inclusive
- Willing and able to adhere to a study visit schedule and study requirements

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 control

• 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

Functional Dyspepsia/Irritable Bowel Syndrome

This is a 12-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 each week for the past month
- Have a documented history of functional dyspepsia
- Able and willing to comply with the study for its duration.

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 Irritable Bowel Syndrome

You may be eligible to participate 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

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

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July 13, 2006
To be determined

August 10, 2006
To be determined

September 14, 2006
Dr. Keith Harvie
"Treatment of Compression Fractures"
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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

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

ABC'S OF LIFE

ACCCEPT DIFFERENCES · **B**E KIND ·

COUNT YOUR BLESSINGS ·

DREAM ·

EXPRESS THANKS · **F**ORGIVE · **G**IVE

FREELY · **H**ARM NO ONE · **I**MAGINE

MORE · **J**ETTISON ANGER ·

KEEP CONFIDENCES ·

LOVE TRULY ·

MASTER SOMETHING · **N**URTURE

HOPE · **O**PEN YOUR MIND ·

PACK LIGHTLY ·

QUELL RUMORS · **R**ECIPROCATE ·

SEEK WISDOM ·

TOUCH HEARTS · **U**NDERSTAND ·

VALUE TRUTH · **W**IN GRACIOUSLY ·

XERISCAPE · **Y**EARN FOR PEACE ·

ZEALOUSLY SUPPORT A WORTHY CAUSE



Woman to Woman

By
Julia Chavez, CNP

Cholesterol and You

Everyone wants to know what their cholesterol level is, but why should you know and what are you going to do about it?

Cholesterol is a fat-like substance in the blood. It can build up inside your arteries and this build-up is called plaque. Over time the arteries become narrowed and blood flow to the heart is slowed down due to the plaque. The restricted flow of oxygen-rich blood to the heart can cause chest pain and coronary artery disease. If it becomes completely blocked, the result is a heart attack.

Cholesterol is measured by a blood test called a lipid or lipoprotein profile. You must fast for 8-12 hours before the test. The test shows your total cholesterol level and also the levels of different types of cholesterol and blood fats. Total blood cholesterol should be less than 200. The LDL ("bad") cholesterol builds up in the lining of your arteries which restricts blood flow. Your LDL should be as low as possible. The HDL ("good") cholesterol protects against heart disease. It should be as high as possible.

Triglycerides are another form of fat in your blood that if very high, raise your risk of heart disease. The optimal level of triglycerides is not well established.

Some hereditary factors that affect cholesterol are beyond your control. But there are things you can do to cut the cholesterol in your blood. You can reduce fat in your diet, especially saturated and trans fat. You can increase the fiber in your diet. You can reduce your weight, increase your activity level and stop smoking. If all of these fail, you may need to take a medication.



10 Thoughts on Whole Living

By *Terri Trespicio*

body + soul magazine

1. Allow yourself to *experience* the first delicious moments of morning. Wake up slowly.
2. Live in *tune* with your body; there is no single portrait of health.
3. Deep renewal comes from *resetting* your rhythms.
4. Your energy doesn't run out— it gets blocked. Find ways to free your flow.
5. Bodies in motion tend to stay in motion. Keep yours *moving*.
6. Positive change aligns with your deepest *values*.
7. With each challenge comes new growth. Engage in rewarding efforts.
8. Share your *strengths*—and be open to others' gifts.
9. There is no substitute for *rest*. Get plenty.
10. Surrender our need to control; let yourself be amazed.

Let yourself fall into step with the rhythms of nature. Take an energizing walk, or just go outside and fill your lungs with fresh air.

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki— I have been taking medication for osteoporosis for 2 years. The most recent bone density test shows no change. My doctor tells me the medicine is not working and I need to change to something else. What should I do? Anna C. Albuquerque, NM.

Dear Anna— The situation you describe is a common one, and may not be as bad as it appears. In fact, it may be good. Let me explain.

First of all, no medicine will work if it is not taken regularly and correctly. This is particularly important for the class of drugs called bisphosphonates (Fosamax, Actonel, Boniva). These drugs are so poorly absorbed from the intestinal tract that under the best of circumstances, only about one-half of 1% actually gets into your blood stream, and only one-half of that sticks to your bones and has a chance to work. If there is any food, drink, vitamin, calcium, or other pills in your stomach at the same time the medicine is there, then the

medicine may attach to these things and never be absorbed.

Secondly, remember to continue with a good intake of calcium and vitamin D in order for the medicine to work, since these are the building blocks for healthy bones.

Thirdly, you cannot expect to have an optimal response to medication if you have developed some other disease, such as an overactive thyroid, that might have an effect on your bones.

Finally, even if all of the above are not a problem with you, research studies have shown that stability of bone density in patients taking osteoporosis medication is associated with increased bone strength and reduced risk of fracture. This is because these medications have an effect on your bone metabolism that makes bones stronger at the microscopic level, despite no change in bone density.

There are a few simple tests, in addition to the bone density test, that show how well the medicine is really working.

Sincerely,
Mike Lewiecki

OSTEONECROSIS OF THE JAW

There has recently been a rash of publicity about a problem called osteonecrosis of the jaw (ONJ). This most often appears as an open sore in the mouth after oral surgery or a tooth extraction in cancer patients who are receiving multiple strong medicines, including very high doses of injected drugs similar to some that are used for osteoporosis.

ONJ has been reported to occur rarely in patients being treated for osteoporosis. While the exact risk is unknown, it appears to be less than 1 in 100,000 patients. This is far less than the risk of having a fracture from osteoporosis, which occurs in about 50 out of every 100 women over the age of 50. Having a hip or spine fracture increases the risk of death and disability. Osteoporosis medication can cut the risk of fracture by about one-half.

The bottom line? The risk of breaking bones and suffering the serious consequences of fractures from osteoporosis is much greater than the risk of ONJ. If you would like to learn more, talk to your doctor.



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.