CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center, Inc.

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Our center is deeply committed to educating the public about osteoporosis. Physical fitness and weight-bearing exercise is an important part of the treatment program for anyone with osteoporosis. We are very pleased to have the opportunity to support an important community event that accomplishes both of these goals.

The Second Annual "Stroll and Roll" for Osteoporosis and Arthritis, and Health Expo, takes place on Saturday, April 27, 2002. It will be held at Riverpoint Sports & Wellness, located at the corner of Coors and Paseo de Norte. There will be a fitness walk, competitive runs, and Health Expo with many educational exhibits.

Osteoporosis and osteoarthritis sound almost the same, but are really two entirely different diseases. Osteoporosis is a disease where bone density and bone strength are low, resulting in high risk of fracture with minimal trauma. It is a silent disease until a bone breaks. Osteoarthritis causes painful joints, often in the knees and hips, and can impair walking. They are both common, and may occur together in the same person. Exercise can be helpful for both diseases. There are good medications that can help with both as well. Please join us at the Stroll and Roll– get educated and have some fun.

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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) 855-5505.

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.

Treatment of Postmenopausal Osteoporosis with PTH

This research study will determine if an investigational drug will increase bone mass and prevent bone fractures in postmenopausal women with osteoporosis. There are 9 visits over an 18-month period. At the time of completion of the study, you will be compensated for your time and travel. Qualifications:
Women age 55 years and older,
Postmenopausal (at least one year since your last menstruation),
Have osteoporosis , and
Cannot be taking any of the following medications: bisphosphonates (Fosamax, Didronel, Aredia, Actonel), estrogen replacement therapy, calcitonin.

Prevention of Postmenopausal Osteoporosis

The purpose of this study is to evaluate whether an experimental new drug is sage and effective for preventing osteoporosis in women who have gone through menopause. Osteoporosis is a condition in some older women where the bones become thin and weak, making them more likely to break. This is a 26½ month long study. Qualifications:
Postmenopausal, 45 years and older,
Not currently taking bisphosphonates, calcitonin, or estrogen,
Do not have osteoporosis, and
Generally in good health.

Treatment of Postmenopausal Osteoporosis

The purpose of this study is to compare placebo and an investigational drug in the prevention of spinal fractures in postmenopausal women. Qualified participants will receive study medications, calcium and vitamin D supplements. Study-related health assessments include physical, bone density tests, spine X-ray, gynecologic exam and mammogram. There are several screening visits to determine eligibility, and every 6 months for up to 5 years. Qualifications:
Ambulatory postmenopausal female, age 60-80,
Anatomy suitable for DXA,
BMD –2.5 to –4.0,
No corticosteroids > 30 days within past year, and
No use of estrogen/progestin containing implants, ever.

Prevention and Treatment of Steroid-Induced Bone Loss

This is a clinical research study is to evaluate the effectiveness and safety of a research study drug given one weekly for the prevention and treatment of bone loss associated with the use of oral glucocorticoids, such as prednisone. This is a 12 month long study. Qualifications:
Man or woman age 18-80, and
Being treated with oral steroids. Certain osteoporosis medications are not allowed during this study.

Prevention of Postmenopausal Osteoporosis

This is a clinical research study of a new investigational medication to determine if it prevents postmenopausal osteoporosis. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 3 years. Compensation up to $350 is available to qualified participants. Qualifications:
Females 60-80 years of age,
At least 5 years postmenopausal,
No evidence of breast cancer,
No spine fracture (within past 12 months) or fracture of both hips,
No hormone replacement therapy within the past 3 months,
No Fosamax, Calcitonin, Miacalcin, Actonel, Didronel within the past 2 years, and
In generally good health.

Type 2 Diabetes Mellitus, Recent Onset

This is a study to evaluate and compare the effects of long-term treatment of diabetes with 3 FDA approved medications– Avandia, Glucophage, Glyburide. Physical exam, office visits, lab tests, electrocardiograms, chest X-rays and medication to treat your diabetes for 4 years will be provided. There will be 21 visits over 4 years. You will be paid up to $550 upon completion of the study. Qualifications:

Age 30 – 75,
Male or female,
Diabetes mellitus diagnosed less than 2 years ago and treated with diet and exercise only,
No liver disease,
No kidney disease,
No daily or intermittent corticosteroid use (oral, IV, or inhaled), and
No other significant health problems.

Type 2 Diabetes Mellitus with Microalbuminuria

This study involves treatment with a combination of diabetes drugs for type 2 diabetic patients who have developed microalbuminuria, in which small amounts of protein are excreted in the urine. There will be approximately 7 visits over 40 weeks. At the completion of the study, you will be compensated for your time and travel. Qualifications:

Age 40-80,
Persistent microalbuminuria,
Previously treated by diet and exercise alone, single agent, or combination therapy, and
No other significant health problems.

Postmenopausal with High Cholesterol

The purpose of this study is to evaluate the efficacy of atorvastatin on bone mineral density and markers for bone turnover in postmenopausal women with dyslipidemia and at risk for osteoporosis. This is a 52 week long study. Qualifications:

Postmenopausal, 40-75 years of age,
High cholesterol,
Not had hormone replacement therapy, and
No history of diabetes.

Osteoarthritis (OA)

The purpose of this research study is to compare the long-term safety and efficacy of acetaminophen in the treatment of pain associated with OA of the hip or knee. There will be a total of 7 visits over a 1 year period. All medical procedures performed during the course of the study are at no charge to you, and you will be paid $40.00 per visit for a total of $280.00 if you complete all visits. Qualifications:

Age 40 – 75,
Male or female,
Symptomatic osteoarthritis of the hip or knee for a minimum of six months duration,
Morning stiffness of less than 30 minutes duration, and
Taking medication for OA at least 3 days a week for at least the past three months.

Gout

This is a research study of an investigational drug designed to decrease serum uric acid in patients with gout. If you have had a reaction to allopurinol, a drug commonly used to treat gout, you may be eligible to participate in the study. You will be paid up to $300 upon completion of this 14-week study. Qualifications:

18 years of age or older,
Male or female,
Elevated uric acid in the blood,
Unable to tolerate allopurinol, and
No other significant health problems.

Calendar of Events

Osteoporosis Support Group

Second Thurs of Every Month at:
St. Joseph Rehab Hospital
Pinon Room
505 Elm NE
Albuquerque, NM

Thurs, Jan 10, 2002, 1:30 PM
St. Joseph Rehab Staff
Pain Management for Osteoporosis–Part 1

Thurs, Feb 14, 2002, 1:30 PM
Happy Valentine's Day
St. Joseph Rehab Staff
Pain Management for Osteoporosis–Part 2

Thurs, Mar 14, 2002, 1:30 PM
Leslie Y. Kranz
Physical Fitness Instructor

Thurs, Apr 11, 2002, 1:30 PM
Fashion Show by Steinmart

Health Fair Exhibit

Fri - Sun, Jan 25-27, 2002
KOB Eyewitness Health Fair
Manual Lujan Building
NM State Fairgrounds
Albuquerque, NM

Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS

Dear Dr. Lewiecki– Can I take Tums with my Actonel? Are there any reactions between the two?
Jill G., Rio Rancho, NM.

Dear Dr. Lewiecki– I spray Miacalcin in my nose every day for osteoporosis. Do I need to take calcium pills too?
Susan B., Albuquerque, NM.

Dear Dr. Lewiecki– What kind of calcium is best?
John R., Pueblo, CO.

I get more questions about calcium than anything else. It can be confusing, because there are so many kinds of calcium on the market, and there is so much you read that gives conflicting advice. It would take many pages to discuss this in detail, but let me give some basic principles here.

1. Calcium is part of the foundation of any program for prevention and treatment of osteoporosis. You must get an adequate amount of calcium every day in order to benefit from any medication. The other components of this foundation are vitamin D and weight-bearing exercise.

2. If you take Actonel or Fosamax, it is very important to get enough calcium every day, but you cannot take it at the same time you take your medication. Calcium, or food, in your stomach will prevent the Actonel or Fosamax from being absorbed into your bloodstream.

3. Miacalcin is not calcium, and does not have any calcium in it. For Miacalcin to work, you must get enough calcium every day.

4. Most kinds of calcium are fine. I suggest starting with either calcium carbonate or calcium citrate. Take no more than 500-600 mg at one time, and take it with meals to help with absorption. It will work even if you have a problem with low stomach acid or take medications to reduce stomach acid.

5. Too much calcium can be harmful. I recommend no more than 1200-1500 mg per day with diet plus supplements.

Mike Lewiecki

DR. LEWIECKI RECEIVES INTERNATIONAL AWARD

Atlanta, GA, February 21, 2002. The International Society for Clinical Densitometry (ISCD) announced that E. Michael Lewiecki, MD, was selected as "Physician of the Year." This award is presented annually for outstanding contributions and achievements in the field of bone densitometry.

Dr. Lewiecki is an osteoporosis consultant, researcher, and educator in Albuquerque, NM, USA. He is President-Elect of the ISCD, Osteoporosis Director of New Mexico Clinical Research & Osteoporosis Center, and Clinical Assistant Professor of Medicine at University of New Mexico School of Medicine.

The ISCD is a non-profit medical society dedicated to educating healthcare providers about bone density testing for osteoporosis, and maintaining high standards in bone densitometry.

OSTEOPOROSIS FOUNDATION OF NEW MEXICO

The Osteoporosis Foundation of New Mexico needs your support! This is a local non-profit 501(c)(3) foundation established to benefit osteoporosis research and education. Please consider making 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, Executive Director, at (505) 855-5627. Visit the foundation website at:

www.osteoporosisfoundationnm.org.

Osteoporosis Research Study

This is a clinical research study designed to evaluate the effectiveness and safety of Fosamax taken once a week to Evista, which is taken once a day. This study will evaluate the effect that both medications have on osteoporosis by measuring the changes in bone mineral density during treatment with these medications. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 13 months. Compensation is available to qualified participants for study participation. Qualifications:
Female 40 years or older, and
Postmenopausal 6 months, and
Has been diagnosed with osteoporosis, and
No bilateral hip replacements, and
No hormone replacement therapy, and
Certain medications are not allowed.

Diabetic Neuropathy

This is a clinical research study designed to evaluate the safety and efficacy of the investigational use of Trileptal® in patients with neuropathic pain due to diabetic neuropathy. You may qualify for this 12-week trial if you meet all study entry criteria. Qualifications:
Male or female 18 years or older, and
Clinically diagnosed with diabetes mellitus, type 1 or 2, and
Neuropathic pain due to diabetic neuropathy for 6 months to 5 years prior to study entry, and
Females postmenopausal 1 year or more, and
Generally in good health.

Postmenopausal Osteoporosis

This is a clinical research study designed to compare two currently marketed drugs for the treatment of osteoporosis in postmenopausal women on the chance of experiencing fractures. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 5 years. Compensation up to $300 is available to qualified participants. Qualifications:
Females 50-80 years of age, and
At least 2 years postmenopausal, and
No spinal fractures, and
Have not used Estrogen replacement therapy (hormones) within the last month, and
Have no history of cancer, and
Meet all study entry requirements.

Hypertension

This is a clinical research study designed to evaluate the safety and efficacy of once daily oral administration of M100240 in subjects with mild to moderate essential hypertension. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 16 weeks. Compensation is available to qualified participants for study participation.

Qualifications:
Male or female, 18-80 years of age
Females – postmenopausal at least 2 years OR using accepted form of contraception
History of essential hypertension OR newly diagnosed with hypertension
No heart attack within 1 year
Certain diseases and drugs not allowed
Meet all other entry criteria

Woman to Woman

by
Julia Chavez, CNP

Breast Cancer

One out of every eight women will develop breast cancer. Will it be you?

Risk factors for breast cancer include family history (mother or sister with breast cancer), first pregnancy over age 30, and choosing not to breast feed.

Early detection of breast cancer can improve your chances of surviving this disease. First, if you are over age 40, get a mammogram every year. Second, do regular breast self-exams. It takes only a few minutes once a month, and it can make the difference between life and death. Many women think they will not be able to find a lump because their breasts are "too lumpy." My answer to that is that very few women have completely smooth breasts. The purpose of doing the self-exam is to become familiar with your own "lumps and bumps." If you don't get mammograms and do regular breast self-exams, you will probably not discover a lump until it becomes the size of golf-ball. Wouldn't you rather find it when it is the size of a pea?

Thank you to our "old" and "new" patients for the resounding welcome for our nurse practitioner, Julia Chavez. RN, MSN, CFNP

We are very excited to have her as a member of our staff. Her caring manner and professional skills have already made her a popular choice. With her special interest in women's healthcare issues and clinical research, she is the perfect complement to our program of patient care. She has also been essential at providing coverage for the practice when Dr. Lewiecki or Dr. Rudolph is out of town.

If you or a friend are looking for a primary healthcare provider, please consider Julia. She is getting busier all the time, but still is able to take on new patients and "walk-ins." And, if you have not yet met Julia, please stop in to say hello. She will be happy to take a few minutes from her regular duties to talk with you.

Obesity with Untreated High Cholesterol

This is a clinical research study designed to assess the effect of a new investigational drug in the treatment of obesity in subjects who have untreated high cholesterol. If you meet all study entry criteria you may be eligible to participate in this 1-year study. Compensation is available to qualified participants. Qualifications:
Male or female, 18-70 years of age, and
No significant health problems, and
Untreated high cholesterol levels, and
No anti-obesity drugs within the last three months, and
No weight loss treatments, such as very low-calorie diet in last six months, and
No history of surgical procedures for weight loss or laxative abuse, and
Meet all other entry criteria.

Pneumonia

This is a clinical research study designed to assess the safety and efficacy of oral Augmentin 2000/125 mg twice daily for 7 days in the treatment of adults with bacterial community acquired pneumonia. You may qualify for this 4-week trial if you meet *all* study entry criteria. Compensation is available to qualified participants. Qualifications:
Male or female, 16 years or older, and
Clinical and radiological diagnosis of community acquired pneumonia, and
No allergy to penicillin, penicillin-related antibacterials or beta-lactam antibiotics
No lowered immune system, and
Females – not pregnant or lactating.

Treatment of Postmenopausal Osteoporosis

The purpose of this study is to compare placebo and an investigational drug in the prevention of spinal fractures in postmenopausal women. Qualified participants will receive study medications, calcium and vitamin D supplements. Study-related health assessments include physical, bone density tests, spine X-ray, gynecologic exam and mammogram. There are several screening visits to determine eligibility, and every 6 months for up to 5 years. Qualifications:
Ambulatory postmenopausal female, age 60-80,
Anatomy suitable for DXA,
BMD –2.5 to –4.0,
No corticosteroids > 30 days within past year, and
No use of estrogen/progestin containing implants, ever.

Postmenopausal Osteoporosis

This is a clinical research study designed to compare two currently marketed drugs for the treatment of osteoporosis in postmenopausal women on the chance of experiencing fractures. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 5 years. Compensation up to $300 is available to qualified participants. Qualifications:
Females 50-80 years of age, and
At least 2 years postmenopausal, and
No spinal fractures, and
Have not used estrogen replacement therapy (hormones) within the last month, and
Have no history of cancer, and
Meet all study entry requirements.

 All study-specific information is IRB approved. To learn more about any study, call (505) 855-5505.