CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

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

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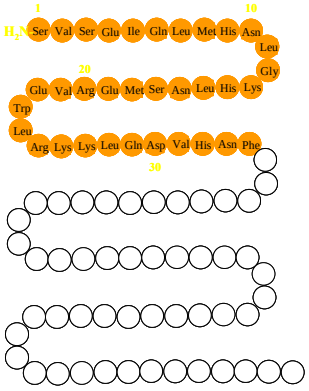
New Bone Building Drug Approved by FDA

On November 26, 2002, the Federal Drug Administration announced the long anticipated approval of teriparatide, a new osteoporosis drug with the brand name of Forteo™. This is the first of an exciting new class of drugs, called anabolic agents or "bone builders," for the treatment of osteoporosis.

Bone is a living organ that is continually renewed through a process of bone turnover, where bone is being resorbed (dissolved) and formed. When there is more resorption than formation, bone density goes down and osteoporosis can develop. Up to this time, all of the drugs used have been in the antiresorptive class, where bone resorptive is slowed down. These drugs (alendronate, risedronate, raloxifene, and calcitonin) can increase bone density and reduce the risk of osteoporotic fractures.

However, for many years physicians have wanted to have a medication to increase bone formation, and thereby do even more to help with osteoporosis. Now, for the first time, we have a drug that will do this. Research studies have shown that teriparatide can increase bone density and reduce the risk of osteoporotic fractures in women with postmenopausal osteoporosis. It has also been shown to increase bone density in men with "primary" osteoporosis or osteoporosis due to low male hormone levels. It is given by daily injections at home with a "pen," similar to the ones that diabetics use to inject insulin. It will probably be given for no more than two years in most patients, and is only for those with very severe osteoporosis problems.



Molecular Structure of rhPTH

Teriparatide is also called recombinant human parathyroid hormone 1-34, or rhPTH (1-34). It is an exact duplicate of a portion of PTH that is naturally made by our parathyroid glands. This drawing shows a circle for each of the 84 amino acids of natural human PTH, with darkened circles for the 34 amino acids of rhPTH (1-34).

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.

Once a Year Treatment - Postmenopausal Osteoporosis

This is a clinical research study to evaluate the effectiveness and safety of a once a year intravenous dose of an investigational medication in reducing the risk of fracture in postmenopausal osteoporotic women. You may qualify for this 3-year trial if you meet all study entry criteria.

Qualifications:
Postmenopausal women, ages 65 to 89, and
Can currently be taking Hormone Replacement Therapy / Estrogen Replacement Therapy (Selective Estrogen Receptor Modulator's) or calcitonin, and
Not taking oral bisphosphonates, fluoride, tibolone or parathyroid hormone, and
No bilateral hip replacement or use of hip protectors, and
Meet all other entry criteria.

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.

Postmenopausal Osteoporosis

This is a clinical research study designed to compare the efficacy and safety of intravenous and oral administrations of an investigational drug in women with postmenopausal osteoporosis. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 24 months. Compensation is available to qualified participants.

Qualifications:
Women ages 55 - 80
At least 5 years postmenopausal
No malignant disease diagnosed within the previous 10 years
No breast cancer diagnosed within the past 20 years
No use of oral hormone replacement or bisphosphonate therapy within the last six months
No allergies to bisphosphonates
Meet all study entry requirements.

Migraine Headache

This is a clinical research study designed to evaluate the effectiveness and safety of zonisamide as prophylactic treatment in subjects with migraine headaches. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 20 weeks. Compensation is available to qualified participants for study participation.

Qualifications:
Male or female, 18-65 years of age.
Have at least 4 migraine attacks per 28 days, each attack separated by 48 hours.
Do not use more than 3 different medications for control of a single migraine within 3 months.
No allergy to sulfonamides (sulpha-based medication).

Type 2 Diabetes Mellitus

This is a clinical research study designed to determine the efficacy, safety, tolerability, and pharmacokenetics of an investigational drug in patients with type 2 diabetes mellitus. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 18 weeks. Compensation is available to qualified participants for study participation.

Qualifications:
Male or female, 35 - 75 years of age
Diagnosed with type 2 diabetes mellitus more than 3 months.
No uncontrolled hypertension.
No heart attack within last 6 months.
Women - cannot be pregnant or lactating and must be using an acceptable form of contraception.

Breast Density in Premenopausal Women

This is a clinical research study designed to determine if the application of an experimental drug (4-OHT Tamoxifen gel) will improve the reading and interpretation of your mammogram by decreasing breast density (whiteness in the film). You may qualify for this 6-month trial if you meet all study entry criteria.

Qualifications:
Premenopausal women ages 18-45
50% - 80% density in breast tissue by mammography.
Normal menstrual cycles.
No hormones or steroids within the last 3 months.
No breast surgery within the last 2 years.
Meet all other entry criteria.

Anorexia Nervosa

This is a clinical research study designed to evaluate the effect of an investigational drug on bone mineral density in pediatric subjects with anorexia nervosa. If you meet all study entry requirements you may be eligible to participate. The study will last approximately 13 months. Compensation is available to qualified participants.
Qualifications:

Females, under 17 years of age
Have symptoms consistent with anorexia nervosa
No longer having menstrual cycles
Non-smoker or smokes ≤ 15 cigarettes per day
No recent history (within 12 months) of alcohol or other substance abuse
Must have parental consent
Meet all other requirements

Calendar of Events

Osteoporosis Foundation of New Mexico
Albuquerque
Osteoporosis Support Group

Free
Educational
Presentations
Second Thursday of every month

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

PREVENTING
OSTEOPOROSIS

- ☐ Thursday, January 9, 2003
- ☐ Thursday, February 13, 2003
- ☐ Thursday, March 13, 2003

The support group is open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want, and it is FREE. 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 am 74 years old and have osteoporosis. I have had two fractures in spine over the last 3 years. I just read in the newspaper that a new injectable drug was approved for osteoporosis. I am now taking a pill once a week without any problem. Should I ask my doctor to give me the new medications?
Caroline B., Raton, NM.

News travels fast when a new treatment for osteoporosis becomes available. You are referring to teriparatide, or rhPTH, sold under the brand name of Forteo™. For more information on this exciting new drug, see the front page of this newsletter.

The question you raise is a very important one– that is, who is most likely to benefit from this drug? The answer is not entirely clear at this time, and what I say about this now may change by next year. It is helpful to look at the package insert approved by the FDA. This says that teriparatide is "indicated for the treatment of postmenopausal women who are at high risk for fracture. These include women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy." It goes on to say that the drug is also "indicated to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture."

As for you- you certainly are a very high risk for fracture, considering your known osteoporosis and the fact that you have already had several fractures. I would consider you a possible candidate for treatment with teriparatide. However, the final decision on this depends on a number of other factors, such as your response to the current treatment, as measured by changes in bone density or laboratory tests. You need to be physical able to give yourself injections, or find someone else to do. And the cost of the new drug, which may be high, should be considered.

Mike Lewiecki

RESPONSE TO OSTEOPROSIS TREATMENT

A common issue facing physicians and patients alike, is this: How do we know if a treatment for osteoporosis is working? After all, what we are trying to do with treatment is prevent fractures. If there is no fracture, then nothing happens. It is hard to measure "nothing". And you may not have had a fracture even if you were not taking medications.

In an individual patient, we need to measure something that is a "surrogate" for bone strength that is somehow related to the risk of having, or not having, a fracture. The best way to do that today is by measuring bone density. We would like to see an increase in bone density to be sure your bones are getting stronger. In fact, the greatest reductions in the risk of fracture seem to be associated with the largest increase in bone density.

What if your bone density does not go up? This is not as bad as it seems. There is good evidence that stability, or no change, in bone density is also associated with reduced risk of fracture. This is because drugs may strengthen bones by changing their "quality" as well as the density. If bone density goes down, that is cause for concern, and is usually cause for further investigation.

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 Elizabeth Ortega Rangel, Executive Director, at (505) 341-0705. Visit the foundation website at:

www.osteoporosisfoundationnm.org.

Constipation-Predominant IBS

This is a clinical research study designed to evaluate the effectiveness and safety of an investigational drug, Dexloxiglumide, in female patients with constipation-predominant irritable bowel syndrome. 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:
Females 18-70 years of age.
2 years postmenopausal, surgically sterile or practicing acceptable method of contraception..
No daily use of laxatives or laxative abuse.
No abdominal surgery (exception appendectomy or cholecystetomy).
Generally in good health.

Postmenopausal Women with Low Bone Density

This is a clinical research study designed to determine the efficacy, safety, and tolerability of an investigational drug for postmenopausal women with low bone mineral density. If you meet all study entry criteria you may be eligible to participate. The study will last approximately 2 years. Compensation is available to qualified participants for study participation.

Qualifications:
Women not more than 85 years of age.
At least 1 year postmenopausal.
No bisphosphonate use within the last 12 months.
No hormone replacement therapy, selective estrogen receptor modulators, and certain other medications used within last 6 months.
Meet all other entry criteria.

Insomnia

This is a clinical research study designed to assess the long-term safety and efficacy of a new investigational drug in adult patients with primary insomnia. If you meet all study entry criteria you may be eligible to participate. The study with last approximately 8 months. Compensation is available to qualified participants for study participation.

Qualifications:
Male or female, 21 to 64 years of age.
Three months history of primary insomnia.
Have used or are currently using sleep aid medications at least four times per month.
No significant illness.
No sleep disorders, e.g., sleep apnea, narcolepsy.
Meet all other entry criteria.

Woman to Woman

by
Julia Chavez, CNP

Extra Pounds Weighing You Down?

If all the extra weight you gained during the holidays is bothering you, this is a good time to think about losing it. I will not recommend a specific diet and in fact recommend that you avoid fad diets.

You will read and hear about all the "quick fix" diets at this time of year. It has been my experience that fad diets will give you temporary weight loss and are not usually healthy for you.

The healthiest "diet" is to cut down on the amount you eat. Watch your fat and calorie intake and increase your activity level.

This is weight loss for life and is much easier to maintain.

Medical practice continues to grow for Julia Chavez, CNP

Julia has adjusted well with her move from Espanõla to Albuquerque. She is enjoying life in her new professional and personal environment, and thanks all of you for helping her.

Now that more and more people have discovered that she is an experienced and compassionate healthcare provider, her medical practice is growing fast. As busy as she is, she is still able to see urgent problems for patients of Dr. Lewiecki and Dr. Rudolph, and her own patients as well.

If you or a friend are looking for a primary healthcare provider, please consider Julia. 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. She sees all types of adult patients, with a special interest in women's healthcare.

"It is a capital mistake to theorize in advance of the facts."

Sherlock Holmes,
The Adventure of the Second Stain

All medical researchers have a bit of Sherlock Holmes, as well as Dr. Watson in them. Drs. Lewiecki and Rudolph continue to pursue their passion for finding "the facts" in clinical research. They recently presented three new research studies at the 24th Annual Meeting of the American Society for Bone and Mineral Research, held in San Antonio, Texas, from September 20-24, 2002. Here are the titles of these studies and a brief summary of the results:

"How Common is Loss of Bone Mineral Density in Elderly Clinical Practice Patients Receiving Oral Bisphosphonate Therapy for Osteoporosis." The bottom line on this study was that about 10% of patients lost a significant amount of bone density while on treatment with alendronate, risedronate, or etidronate. Half of these "bone losers" turned out to have important, but previously unrecognized, medical problems affecting bone metabolism. The conclusion is that these medicines work well in most patients, and that it is useful to get a follow-up bone density test after starting treatment.

"Oral Bisphosphonates for Treatment of Osteoporosis in Elderly Patients with Impaired Renal Function." These medicines are not usually recommended in patients with kidney problems– not because they don't work or because they cause problems, but because there is no experience with this type of patient. This study showed that about 13% of elderly patients treated with the drugs actually had abnormal kidney function, and that they seemed to respond to treatment as well as those with normal kidney function.

"Ultrasound Bone Density: Classification of Osteoporosis by Absolute Fracture Risk Improves Diagnosis and Treatment." The way that bone density reports are presented to healthcare providers and patients can have an effect on whether or treatment is started. This study showed that giving the report with "absolute fracture risk" instead of the more traditional "T-score" resulted in more patents being recognized as being at high risk for fractures, and more patients being started on treatment.

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