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Participate in a Clinical Trial

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## Denosumab a Promising New Therapy for Osteoporosis

By Dr. David Kendler, Director, Prohealth Clinical Research

What are we looking for in new treatments for osteoporosis? I am often asked if the treatments currently available aren't adequate to meet our needs.

Many people with osteoporosis discontinue therapy before they achieve any demonstrable benefit. Three out of four patients who start treatment stop taking it within a year. Clearly, it would be useful to have a treatment option that would increase the likelihood that patients with osteoporosis will remain on therapy.

Why do people stop taking their osteoporosis therapy? Some have side effects, some can't afford the therapy, and some don't understand why they are taking it in the first place.

Denosumab is likely to be our next approved treatment for osteoporosis, and has been a focus of our research program for the past five years. This medication is a human monoclonal antibody against RANK Ligand, given by injection under the skin every six months. It slows the formation of osteoclasts, the cells that remove old bone, and therefore normalizes the overactive bone turnover typical of women with osteoporosis. Although the end result of slowing bone turnover is the same as with other products (such as Fosamax (alendronate) and Actonel), the way denosumab acts is quite different. Fosamax kills the bone-resorbing cells, while denosumab slows the formation of these cells. With this different mechanism, we see different clinical effects. In addition, because denosumab is a human monoclonal antibody, the body does not recognize it as foreign. It is similar to natural antibodies already circulating in every healthy individual and effectively "immunizes" against excessive bone turnover.

The Research Centre has now participated in a number of trials with this agent. Prevention trials have shown that denosumab prevents bone loss in women likely to experience it after menopause. Treatment trials have shown that, in postmenopausal women with osteoporosis, the twice-yearly denosumab injections not only increase bone density but also prevent fracture of spine, hip, and other bones at least as well as any other therapy.

But doctors and patients often ask for more information. They want to know whether this new therapy is better than existing therapy. The DECIDE trial demonstrated that denosumab was better at

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## Overnight Cheddar Bagel Casserole

The perfect make-ahead breakfast for a crowd

Courtesy of Osteoporosis Canada

From The Everyday Calcium Cookbook by Helen Bishop  
MacDonald © 2004

### Serves 8

**13 x 9 x 2 (3.5 L) shallow baking dish, greased**

- 4 plain bagels
- 2 cups (500 mL) shredded cheddar cheese
- 1 1/2 cups (375 mL) diced ham
- 1/2 cup (125 mL) diced red pepper (about 1/2 medium)
- 1/2 cup (125 mL) diced green bell pepper (about 1/2 medium)
- 1/2 cup (125 mL) thinly sliced green onions (about 4 medium)
- 3 tbsp (45 mL) butter
- 9 eggs
- 2 1/2 cups (625 mL) milk
- 2 tbsp (30 mL) Dijon mustard
- 1 tsp (5 mL) salt
- 4 oz (120 g) cheddar cheese, thinly sliced

1. Cut bagels in half, so that each half resembles a half moon. Turn each half moon on its side and cut into 6 thin slices. Arrange half the bagel slices along the bottom of the baking dish.
2. In a large bowl, combine cheese, ham, red and green peppers, and onions; sprinkle over bagel layer.
3. Butter one side of remaining bagel slices and arrange slices, buttered side up, on top of cheese mixture.
4. In a large bowl, whisk together eggs, milk, mustard, and salt; pour evenly over bagel mixture. Cover with plastic wrap and refrigerate overnight. Remove from refrigerator one hour before baking.
5. Preheat oven to 350° F (180° C). Bake uncovered in preheated oven for 1 hour, or until a knife or toothpick inserted in centre comes out clean. If top is browning too quickly, cover loosely with foil.

**TIP:** Try a variety of bagels for this recipe. Onion and poppy seed work well.

Per serving: calories 484; protein (g) 29.9; carbohydrates (g) 28.3; fat (g): sat 14.8; mono 8.5; poly 2.

## Free Bone Density Testing

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## Denosumab a Promising New Therapy, cont'd

increasing bone density and normalizing bone turnover than alendronate (Fosamax). The STAND trial demonstrated that changing from alendronate to denosumab was not only safe, but led to further gains in bone density as compared to continuing on alendronate.

By the time Health Canada and FDA approve this therapy, we will have proof that denosumab is effective in preventing all osteoporotic fractures, is a very specific therapy with few side effects, and has demonstrated superiority over existing therapies.

Thanks to the multicentre trials that a number of our volunteers have participated in, we will likely soon have a safe, more effective, and more convenient therapy for women with postmenopausal osteoporosis.

## Would you like to participate in a clinical trial?

We at the Research Centre are always starting new trials and recruiting volunteers. Now that we have expanded into the areas of diabetes, osteoarthritis, and rheumatoid arthritis, we have something for almost everyone. Our volunteers have a chance to use the newest drugs at no cost, while benefiting from medical exams, tests, and of course reimbursement for travel expenses. If you are interested in participating in a trial or would like us to keep your name on our mailing list for future trials, please call us, e-mail us, or find the latest information on our website.

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If you know of a location or community event where we can provide more information on our studies, or if you know anyone who might be interested, please call us at 604-263-3661 or toll free at 1-866-226-6143. You can also visit us on the web at [www.prohealthcr.ca](http://www.prohealthcr.ca) or e-mail us at [prohealth@prohealthcr.ca](mailto:prohealth@prohealthcr.ca).