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Cochrane Database of Systematic Reviews 2003, Issue 4. Art. No.: CD004523.
DOI: 10.1002/14651858.CD004523.

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[Intervention Review]

Risedronate for the prevention and treatment of postmenopausal osteoporosis.

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Editorial group: Cochrane Musculoskeletal Group.
Publication status and date: Unchanged, published in Issue 4, 2005.

Citation: Cranney A, Adachi JD, Guyatt G, Papaioannou A, Robinson VA, Shea BJ, Tugwell P, Waldegger LM, Weaver B, Wells G, Zytaruk N. Risedronate for the prevention and treatment of postmenopausal osteoporosis.. *Cochrane Database of Systematic Reviews* 2003, Issue 4. Art. No.: CD004523. DOI: 10.1002/14651858.CD004523.

ABSTRACT

Background

Postmenopausal osteoporosis results in an increased susceptibility to low-trauma fractures due to reduced bone volume and microarchitectural deterioration. Risedronate, a third generation bisphosphonate, has been shown in multiple clinical trials to reduce fracture risk and improve bone mineral density in postmenopausal women with osteoporosis. First and second generation bisphosphonates are known to have gastrointestinal side-effects and risedronate may be better tolerated.

Objectives

To systematically review the efficacy of risedronate on bone density, and fracture reduction in postmenopausal women.

Search methods

The Cochrane Controlled Trials Registry Medline, and Current Contents were searched from 1990 - 2001. The electronic search was supplemented by handsearching four osteoporosis journals and their conference proceedings, as well as contacting content experts and industry sources for unpublished data.

Selection criteria

We included eight trials that randomised women to risedronate or an alternative (placebo or calcium and /or vitamin D) and measured bone mineral density for at least one year.

Data collection and analysis

For each trial three independent reviewers assessed the methodological quality and abstracted data. Data was extracted for outcomes of fracture, bone mineral density and adverse events. The more conservative random effects model was used to pool data. The quality of trials was assessed according to the Jadad five-point scale.

Main results

Both vertebral and non-vertebral fractures were statistically and clinically reduced with risedronate. Eleven out of one hundred women who received risedronate had a vertebral fracture compared to 17 out of one hundred of those who received calcium and vitamin D (pooled relative risk for vertebral fractures of 0.64 (95% CI 0.52 - 0.77). Three percent of participants who received risedronate had a non-vertebral fracture compared to 4.6% of those who received calcium and vitamin D (pooled relative risk for nonvertebral fractures of 0.73 (95% CI 0.61 - 0.87). The weighted mean difference for the percent change from baseline for bone mineral density with 5 mg daily for lumbar spine, femoral neck and trochanter was 4.54% (95%CI 4.12 - 4.97), p<0.01; 2.75% (95% CI 2.32 - 3.17), p<0.01; and 4.38% (95% CI 3.51 - 5.25), p<0.01 respectively.

Authors' conclusions

There is good evidence for the efficacy of risedronate in the reduction of both vertebral and non-vertebral fractures. In addition, there is evidence from randomized trials that risedronate is able to achieve this without increasing risk for overall withdrawals due to adverse effects.

PLAIN LANGUAGE SUMMARY

HOW WELL DOES RISEDRONATE WORK TO TREAT AND PREVENT OSTEOPOROSIS IN WOMEN AFTER MENOPAUSE?

To answer this question, scientists found and analysed 8 high quality studies. These studies tested over 14 500 women after menopause who had mild or severe bone loss or a break. Women received a placebo (sugar pill) with or without calcium with vitamin D, or 5mg of risedronate daily. These studies provide the best evidence we have today.

What is osteoporosis and how can risedronate help?
Osteoporosis is a condition of weak brittle bones that break easily. In osteoporosis, breaks or fractures of the spine and hip or wrist (non-spinal fractures) may occur and often without a fall. Risedronate is a bisphosphonate - a drug that is often prescribed to women after menopause to decrease fractures (or breaks) by slowing the loss of bone. There is some debate about whether risedronate decreases all types of fractures and whether it causes few side effects.

How well did risedronate decrease fractures and increase bone density?
After 3 years, fewer women after menopause have spine or non-spinal (such as wrist or hip) fractures when receiving risedronate than a placebo.
-11 out of 100 women taking risedronate versus 17 out of 100 with a placebo had a spine fracture
-3 out of 100 women taking risedronate versus 5 out of 100 with a placebo had a non-spinal fracture.

Over 3 years, bone mineral density in the spine and hip increased more in women taking 5 mg of risedronate daily than in women taking a placebo or calcium and vitamin D.

Were there any side effects?
Side effects such as nausea, stomach upset or pain, and diarrhea may occur. However, the number of people who stopped taking risedronate due to side effects was about equal to the number of people who stopped taking a placebo.

What is the bottom line?
There is "platinum" level evidence that in women after menopause, risedronate at 5mg daily over 3 years decreases spine and non-spinal fractures.

After 3 years, risedronate 5 mg increases bone density in the spine and hip.

Most women do not appear to have side effects that would cause them to stop taking risedronate.