

Zoledronic acid reduces the recurrence of breast cancer in post-menopausal women

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A trial investigating the use of zoledronic acid to aid chemotherapy for breast cancer has found a significant benefit for post-menopausal women, according to results presented at the 2011 European Multidisciplinary Cancer Congress today. Researchers think it could be the key for a greater understanding of the mechanisms of breast cancer recurrence as well as offering new options for patient care.

Zoledronic acid is one of the [bisphosphonates](#), a group of drugs mainly used to treat osteoporosis. However they are also given to cancer patients to protect against the effects of secondary bone cancer, such as pain and weakness in the bones. Laboratory studies have suggested that [zoledronic acid](#) might also have direct anti-tumour effects and enhance other chemotherapy treatments, so the multi-centre AZURE trial was set up to investigate further.

Led by Professor Robert Coleman at the Weston Park Hospital in Sheffield, UK, the trial recruited 3,360 patients with stage II/III [breast cancer](#) from 174 centres. They were randomised to receive chemotherapy and/or endocrine therapy, with or without zoledronic acid. An interim analysis of the trial's progress indicated that patients were seeing no [clinical benefit](#) from the treatment, so the data were released for more detailed scrutiny.

This confirmed the drug's lack of impact, apart from in a sub-set of women who had undergone menopause five or more years previously. Here, the overall survival rate was 85% compared to 79% for women

who did not receive zoledronic acid. The effect was independent of the characteristics of the disease as shown by the stage of the tumour, oestrogen receptor status, and lymph node involvement.

"This is a small but significant increase," Prof Coleman explains. "The finding is not sufficient to be taken up on its own but in the context of other studies and additional data anticipated later in the year, it is likely to change practice."

The results shed new light on the role that the bones may play in the progress of the disease. "The effects on metastasis and recurrence outside bone suggests that the [bone marrow](#) is an important sanctuary for tumour cells which can be activated after, sometimes, many years of dormancy," Prof. Coleman says. "With help from bone marrow stem cells, they may then spread via the blood stream to set up metastases at other sites."

Even if this is the case, it is still not clear why zoledronic acid is having a beneficial effect. Prof Coleman speculates that it may alter the balance of substances such as cytokines and growth factors that control the bone marrow micro-environment. In this altered state the ability of cancer cells to leave the bone marrow and move to other parts of the body may become dependent on the presence of reproductive hormones.

"Presumably, these changes are only clinically relevant in the context of low levels of female reproductive hormones that we see after menopause," he says.

Further work will be required to establish whether or not this is the case. "We plan to use new, more clinically relevant, animal models of metastasis to assess the early events in the spread of cancer and effects of treatments like zoledronic acid," Prof Coleman says.

Dr Coleman's presentation to the congress coincides with the

simultaneous publication of a paper about the research in the *New England Journal of Medicine*.

President of ECCO, Professor Michael Baumann, said: "It is important to note that so-called 'negative trials', that is trials that do not show the anticipated improvement in the endpoint selected, can yield very important information for further trials and also can feed important information back into preclinical research. Eventually negative trials, even if initially very disappointing for the investigators, can make important contributions to cancer research and to practice-changing new strategies relevant for [cancer patients](#)."

Commenting on the study, which he was not involved with, ESMO member Professor Christoph Zielinski from the Medical University of Vienna, Vienna, Austria, said: "Whereas the earlier data from the AZURE trial did not show any influence of zoledronic acid upon outcomes in an unselected patient population, the present results show that post-menopausal patients do benefit from this treatment approach. These data are similar to the ABCSG 12 data reported earlier in which hormonal medication was given to premenopausal patients to induce premature menopause. Taken together, the two trials thus add up to a high level of evidence of a benefit of the addition of zoledronic acid to adjuvant therapy for early breast cancer in either naturally or medically induced [postmenopausal women](#)."

Provided by ECCO-the European CanCer Organisation

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