



MEDIA RELEASE

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“a milestone in breast cancer control”

NEW PROOF THAT TAMOXIFEN CAN PREVENT BREAST CANCER

Tamoxifen can reduce the risk of breast cancer by 38 per cent in healthy women with a high chance of developing the disease, according to a new study announced today by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) and to be published in the front-line scientific journal *The Lancet* on Saturday.

A team of researchers, led by Professor Jack Cuzick from Cancer Research UK and Professor John Forbes, Group Coordinator of the ANZ BCTG, conducted an extensive review of tamoxifen's track record in prevention trials and found that the number of breast cancer cases dropped significantly in women who were given the drug.

Early results from trials testing tamoxifen as a preventive drug for breast cancer produced mixed results - now the new evidence clearly shows that tamoxifen can successfully reduce the risk of the disease.

The researchers also looked at one trial of raloxifene – an osteoporosis drug for women with osteoporosis – and found that it reduced the incidence of breast cancer by 64 per cent.

They analysed results from four trials, involving 28,000 women that tested the role of tamoxifen as a preventive treatment and one, involving 7,700 women, using raloxifene. The trials compared the performance of the drugs with a placebo.

They also looked at nine trials involving 15,000 women who had a tumour removed from one breast and were treated with tamoxifen to prevent cancer returning.

Researchers calculated the reduction in breast cancer incidence and found it fell in both the raloxifene and the tamoxifen trials. The reduction found was 38 per cent ($p < 0.0001$).

Study Chairman for the Australian contribution to one of the prevention trials IBIS, Professor John Forbes of The University of Newcastle said: “We combined all the available evidence from trials using tamoxifen for breast cancer prevention – collectively involving over 40,000 women - and it is clear to us now that the drug can reduce the chance of high-risk women developing the disease.”

In the trials using tamoxifen for treatment of breast cancer after an initial tumour had been removed, researchers found that the number of new cancers in the opposite breast dropped by 46 per cent.

Tamoxifen was only able to prevent breast cancers that carry receptors for the hormone oestrogen. There was no reduction in incidence for women with oestrogen receptor negative breast tumours.

Researchers also calculated the risk of side-effects from the treatments and found that women on all of the trials taking tamoxifen or raloxifene had an increased risk of developing blood-clotting disorders – with a more than two-fold increased risk seen for both drugs.

The study also found that women taking tamoxifen had a two-fold increased risk of developing endometrial cancer – a much less common cancer than breast cancer – occurring in the lining of the womb. But the trial of raloxifene showed no increased risk of the disease.

There was no difference in overall death rates in the overview analysis between tamoxifen and placebo. There was no excess of death from endometrial or other cancers, or cardiac and vascular events except for pulmonary embolism (six versus two in the prevention trials and eight vs three in the treatment trials).

Professor Forbes said: “The evidence to date clearly shows that tamoxifen can reduce the risk of those breast cancers stimulated by the hormone oestrogen. However, it is crucial that we follow all the trials to their conclusions and find ways to reduce the side-effects of tamoxifen before we can recommend that high-risk women take the drug routinely to prevent breast cancer.”

"It may be possible to reduce side-effects of tamoxifen by using a lower dose or adding low dose aspirin. Carefully selecting women to exclude those already at risk of blood clotting disorders or endometrial cancer may also be a way of making the use of tamoxifen more viable."

"The early data on raloxifene looks very promising – the trial shows that the drug can reduce the risk of breast cancer by 64 per cent and cause fewer side-effects than tamoxifen. We will be awaiting the results of its direct comparison with tamoxifen in the American STAR trial with great interest."

"The future challenges for prevention research are to find ways to reduce the side-effects of tamoxifen and investigate new agents such as aromatase inhibitors. One such drug, anastrozole was found to prevent 70 per cent of new tumours in the opposite breast when used as treatment for postmenopausal women with breast cancer," he said.

Professor Linda Reaby, Associate Professor of Nursing at The University of Canberra and Chair of the ANZ BCTG Consumer Advisory Panel said: "These new results are very important for women worldwide. To know with confidence that some women can have breast cancer prevented is one of the key milestones of the last 25 years. It is very heartening that several thousand women from Australia have contributed to this research through the ANZ BCTG. We now have to get behind the researchers to test new strategies with the potential for less side-effects," she said.

Professor Forbes concluded: "The overview analysis is definitive in terms of prevention of oestrogen sensitive breast cancer by tamoxifen. This provides a secure scientific basis for new prevention research. The real milestones in breast cancer research in the last 25 years have been; 1) chemotherapy and tamoxifen added to surgery improves survival; 2) it is safe for many women with breast cancer to avoid mastectomy; and 3) screening mammography can save lives. Breast cancer prevention is the fourth milestone," he said.

Women who are concerned about their individual risk of breast cancer should consult their doctor.

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A copy of the study to be published in *The Lancet* can be found at the Australian New Zealand Breast Cancer Trials Group website: www.anzbctg.org.

Spokespeople from the ANZ BCTG are available for comment.

**For further information, and for a copy of the paper, please contact: Ms Fiona Tigar, Hill & Knowlton
Ph: (02) 9286 1250, Mobile: 0421 610 624 or Ms Katie Perry, Ph: (02) 9286 1215, Mobile: 0402 226 238**

For interview with Professor John Forbes, please contact:

Jenny Sly, Breast Cancer Institute of Australia, Ph: (02) 4925 3022, Mobile: 0417 233 932

Notes to editors:

The Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) is Australia's national breast cancer research group dedicated entirely to breast cancer research through the conduct of multi-institution clinical trials. The ANZ BCTG collaborates with 300 researchers in over 60 of the leading medical institutions in Australia and New Zealand, and with similar research groups in 15 countries internationally.

The International Breast Cancer Intervention Study (IBIS) is conducted in Australia and New Zealand by the ANZ BCTG and involves 7,139 healthy women at increased risk of breast cancer from the United Kingdom, Europe and Australia and New Zealand (2,674 women from 19 institutions in Australia and New Zealand). IBIS was supported in Australia by the National Health and Medical Research Council.

Breast cancer affects over 10,000 women in Australia each year.

Almost two-thirds of tumours from pre-menopausal women and three-quarters of tumours from post-menopausal women contain detectable oestrogen receptors, which means their growth is stimulated by the presence of oestrogen.

Tamoxifen is effective as a treatment for oestrogen receptor positive breast tumours.

Raloxifene is a drug used for the prevention and treatment of osteoporosis in postmenopausal women.

Aromatase inhibitors are a new class of drug, which can virtually eliminate oestrogen in postmenopausal women by blocking its production.

STAR - Study of Tamoxifen and Raloxifene is recruiting in the United States, Puerto Rico and Canada. The trial will include 22,000 postmenopausal women at increased risk of breast cancer to determine whether raloxifene is as effective in reducing the chance of developing breast cancer as tamoxifen.