

Younger women with advanced breast cancer needlessly excluded from treatment trials

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Pre-menopausal women with the most common type of advanced breast cancer are usually excluded from medical research unnecessarily, according to an expert panel at the Advanced Breast Cancer Fourth International Consensus Conference (ABC 4).

In new guidelines for treating advanced [breast cancer](#) agreed today, the panel said that the majority of clinical [trials](#) for hormone-dependent advanced breast cancer either explicitly exclude pre-menopausal women, or deter them by means of unnecessarily restrictive inclusion criteria. The panel has called for future trials to be designed to enable both pre- and post-menopausal women to be enrolled.

Chair of the ABC 4 conference, Professor Fatima Cardoso, Director of the Breast Unit of the Champalimaud Cancer Centre in Lisbon, Portugal, said: "At present, not only are [younger women](#) denied the opportunity to take part in clinical trials, but also clinicians lack the evidence on how best to treat these patients who have advanced breast cancer with limited therapies available."

Globally, hundreds of thousands of women are being treated for advanced breast cancer, where the tumour has begun to spread to other parts of the body, and around a third of these cancers are in pre-menopausal women. The majority are oestrogen receptor positive (ER positive), meaning that tumour growth is fuelled by the female hormone oestrogen. This subtype of advanced breast cancer has recently seen a major advance with the introduction of drugs called CDK inhibitors

A key [treatment](#) for pre-menopausal women with ER positive advanced breast cancer is to shut down their bodies' production of oestrogen, either permanently by removing the ovaries, or temporarily with drugs. Professor Cardoso said: "This 'induced menopause' means that including these younger women in trials alongside older women is unlikely to hamper the research. On the contrary, it might make it easier to recruit women on to the trial and it might give us more information on how best to treat women of all ages.

"There is no sense in excluding these women from these trials or running separate trials of new treatments for them. The treatment we give them will make them menopausal anyway, so why exclude them in the first place?"

Professor Bella Kaufman treats pre-menopausal patients at the Sheba Medical Center, Tel Hashomer, Israel, and is herself an advanced breast cancer patient. She said: "Although breast cancer is less common in pre-menopausal women, this is an important group of patients who have a complicated set of needs. To understand and address these needs, it's vital that pre-menopausal women take part in [clinical trials](#). Younger patients, for example, may have additional concerns about their fertility, their ability to work, or their body image."

This issue was one of several addressed by 1,300 experts and patients from 88 countries around the world as they agreed new guidelines for the treatment of advanced breast cancer. Other recommendations included clearer advice on the use of complementary medicine.

The guidelines state that alternative therapies used instead of scientifically-based medicines are not recommended at any stage of cancer treatment, but that some complementary therapies, such as exercise, mindfulness and acupuncture, have the potential to reduce symptoms or treatment side-effects.

They said that some alternative treatments show "no effect at best, or even association with worse outcome". Examples of these include antioxidant supplements, Chinese herbal medicine, oxygen and ozone therapy and high doses of vitamins such as C, D and E.

Dr Eric Winer, Director of Breast Oncology at the Dana-Farber Cancer Institute (Boston, USA) and co-chair of the conference, said: "This new set of guidelines offers clarity on the vast amount of research and information available to [women](#) with [advanced breast cancer](#) and the people who treat and care for them. What sets them apart is that they are produced by a partnership of patients and researchers.

"In the end, it is all about listening to our [patients](#) and communicating clearly. Whether we are talking about standard therapies or complementary approaches, we need to ensure that all lines of communication are wide open."

Provided by European School of Oncology

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