Research questions

Study design and protocol

Recruitment

Tailored treatments

Data analysis

Impact

INTERNATIONAL CLINICAL TRIALS DAY

The Breast International Group (BIG) is dedicated to designing the best clinical trials to serve patients' needs

Asking questions patients want us to ask

The needs of patients and their quality of life are central to the activities of BIG. As the largest academic network for breast cancer research in the world, BIG is dedicated to designing the best international clinical trials to serve patients' needs, always taking into account which important patient questions require international collaboration to obtain answers. One of these questions resulted in the POSITIVE trial. Its initial findings indicate that younger women who wish to become pregnant after a breast cancer diagnosis may safely interrupt their endocrine treatment to try to have a child without increasing the risk of their cancer recurring.

Together we will find a cure

BIG spans across more than 70 countries globally and includes over 60 academic research groups and data centres dedicated to breast cancer research. It brings together the world's top breast cancer specialists to conduct studies that would not be possible in just one hospital or country alone. The steering committee of each trial is composed of representatives from the participating academic groups, the sponsor (either a pharmaceutical company or academic group), and patient representatives. They all work together to design and conduct the most effective trial that meets the needs of patients.

Inclusive studies

Certain patient groups, such as the elderly, are underrepresented in clinical trials for breast cancer. Therefore, prominent research and professional organisations like BIG, the European Organisation for Research and Treatment of Cancer (EORTC), and the International Society of Geriatric Oncology (SIOG) are working together to increase awareness about the needs of older patients with breast cancer and advocate for their participation in clinical studies. The APPALACHES study is a trial with a special focus on older patients with breast cancer.

Breast cancer is not one but many different diseases

It is important for patients to understand that breast cancer is not a single disease. Ongoing research in genetic profiling continues to identify multiple different types of breast cancer and clinical trials are key in helping differentiate treatment plans tailored to each patient's tumours.

Better understanding breast cancer and treatments

Data analysis is a crucial aspect of breast cancer trials, as it enables researchers to comprehend the effectiveness and safety of new treatments, identify potential risks, and assess the impact of interventions on patient outcomes. The collection of data is extremely important, as it can pave the way for personalised treatment plans. BIG's most extensive molecular screening initiative is the AURORA research programme, providing a comprehensive collection of clinical and molecular data gathered longitudinally from patients with metastatic breast cancer. This programme is a valuable resource for researchers worldwide.

From research to clinical practice

The results of a trial can lead to new treatments, a de-escalation of therapy, or it can indicate that the research question did not yield the expected outcome, prompting the trial to be terminated or reconsidered. Many of BIG's research efforts are regarded as ground-breaking due to their innovative designs, significant breakthroughs, or their dedication to personalised treatments for the disease. BIG's work does not directly lead to new drugs …but to new treatments, whether with or without drugs.

Co-funded by the European Union

BIG against breast cancer

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The following studies have already had a significant impact in the lives of patients or are expected to do so in the future:

The DCIS study investigated the tailoring of radiation doses and number of treatment schedules in patients with non-low risk DCIS (ductal carcinoma in situ) of the breast. DCIS is characterised by abnormal cells in the milk ducts that have not spread into the breast tissue. The DCIS study showed that, after breast conserving surgery, when higher doses of radiation were given to the area of the breast where the DCIS was located, along with radiation for the entire breast, it greatly decreased the chances of the DCIS coming back in patients with a higher risk. The study also found that a shorter 3-week period of radiotherapy, instead of the standard 5 weeks for the entire breast, did not increase the risk of recurrence.

The OLYMPIA trial assessed the efficacy and safety of the drug olaparib as a new personalised treatment for women who carry a mutation in the BRCA1/2 genes and develop a high-risk, HER2-negative, early breast cancer.
Results showed that these patients could see the risk of death from their breast cancer cut by 32% due to this new treatment.

The APHINITY trial found that adjuvant pertuzumab in combination with trastuzumab and chemotherapy in patients significantly improved the rates of invasive-disease-free survival among patients with HER2-positive, operable breast cancer when it was added to trastuzumab and chemotherapy.

The MINDACT trial gives hope to many women with node-negative or 1-to-3 node positive early breast cancer, showing that many can be spared adjuvant chemotherapy, thereby greatly improving their quality of life.

The POSITIVE study represents a unique opportunity to allow young women who have had hormone-sensitive breast cancer to temporarily interrupt their treatment and try to conceive.

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