

Department of Health

Breast Cancer Clinical Trials - 101

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Why do Clinical Trials matter?

Clinical trial to test potential new combination therapy for aggressive breast cancer

Researchers are recruiting volunteers for a clinical trial they hope will improve survival rates for an aggressive form of breast cancer that affects about 1,500 women each year in New South Wales.

Media Release: 21 June 2022

NSW researchers are calling for volunteers for a new clinical trial to test a new strategy in cancer treatment: using a new therapy to target a 'defence switch' on cancer cells that alerts cancer to the threat of chemotherapy.

The trial aims to improve survival rates for patients with triple negative breast cancer, a treatment-resistant form of cancer that can quickly adapt against chemotherapy.

It will be led by Associate Professor Christine Chaffer and Dr Beatriz San Juan from the Garvan Institute of Medical Research, and Senior Staff Specialist in medical oncology Dr Rachel Dear of St Vincent's Hospital Sydney. The trial will be conducted at The Kinghorn Cancer Centre in Darlinghurst.

Breast Cancer Trials News

Anastrozole and Tamoxifen Both Prevent Breast Cancer for Postmenopausal Women

09/12/2020

Long-term follow-up of the IBIS-II DCIS clinical trial has found that Anastrozole and Tamoxifen are both effective in preventing breast cancer and DCIS, providing more treatment options for postmenopausal women with an early form of breast cancer.

The results were announced at the San Antonio Breast Cancer Symposium in the United States. 2,980 women were recruited to the IBIS-II DCIS clinical trial worldwide, including 178 women at 24 institutions in Australia and New Zealand where the study was coordinated by Breast Cancer Trials.

Breast Cancer Trials News

New treatment reduces deaths by 32% for breast cancer patients with an inherited BRCA1 or BRCA2 gene abnormality

13/03/2022

Breast Cancer Trials News

\$4.9m For New Research To Address Poorer Outcomes of Young Women with Hormone Receptor-Positive, HER2 Negative Early Breast Cancer

10/02/2022

A project that aims to better understand the biology and treatment of young women with breast cancer has received \$4.9 million in funding from the Australian Government.

The funding is part of the Medical Research Future Fund's Rare Cancers, Rare Diseases and Unmet Needs clinical trials initiative, which supports high quality research, and novel and innovative treatments.

The project will include a new clinical trial called OLIO, that is specifically designed for young women with breast cancer. OLIO will be coordinated in Australia by Breast Cancer Trials and aims to address the poor outcomes of young women with hormone receptor-positive, HER2-negative early breast cancer. In addition, a new pathology test that will help identify specific biological features from the patient's tumor sample, will be developed by investigators from the Peter MacCallum Cancer Centre.

Young women with breast cancer have a higher rate of recurrence and death from breast cancer, and the reasons for this are until now unknown. Outcomes for young women can vary according to breast cancer subtype, but it has been demonstrated to be relatively worse in patients with HR+HER2- breast cancers, where molecular testing has identified evidence of homologous recombination deficiency.

Treatment advances as a result of Clinical Trials

- That breast conserving surgery followed by radiotherapy can be a safe alternative to mastectomy for many women diagnosed with early breast cancer.
- The introduction of trastuzumab (Herceptin) for treatment for HER2-positive breast cancer
- That adding a CDK inhibitor, such as ribociclib and palbociclb, to hormone therapy can slow down the progression of hormone positive, HER2-negative metastatic breast cancer.
- That extending aromatase inhibitor treatment from five to ten years can provide further protection against a breast cancer recurrence for women with hormone positive early breast cancer.
- That hypofractionated radiotherapy (i.e. a shorter, more intense course of radiotherapy) may be as effective as conventional radiotherapy for some women aged 50 and over who have cancer at an early stage and who have had breast conserving surgery with clear surgical margins.

Types of Breast Cancer Trials

<p>CHARIOT BCT 1702: CHARIOT</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>A phase II study evaluating efficacy and safety of Ipilimumab and Nivolumab with neoadjuvant weekly paclitaxel after anthracycline based chemotherapy in high-risk primary triple negative breast cancer, followed by definitive surgery and one year...</p> <p>Find out more</p>	<p>Co-SOFT IBCSG 24-02 / BIG 2-02 / ANZ 0701</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>Cognitive Function Substudy investigating cognitive function for patients participating in the SOFT trial in selected centres.</p> <p>Find out more</p>	<p>DECRESCENDO BCT 2002/BIG 19-02: DECRESCENDO</p> <p>Early Breast Cancer</p> <p>Open</p> <p>De-escalation of adjuvant chemotherapy in HER2-positive, estrogen receptor-negative, node-negative early breast cancer subjects who achieved pathological complete response after neoadjuvant chemotherapy and dual HER2-blockade.</p> <p>Find out more</p>	<p>BRCA-P BCT 1801 / ABCSG 50 (BRCA-P)</p> <p>Prevention</p> <p>Open</p> <p>A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, International Phase 3 Study to determine the Preventive Effect of Denosumab on Breast Cancer in Women carrying a BRCA1 Germline Mutation</p> <p>Find out more</p>	<p>Breast MRI Evaluation BCT 2001: Breast MRI Evaluation</p> <p>Early Breast Cancer</p> <p>Open</p> <p>Breast MRI Evaluation: MRI use and impact on diagnosis, pre-surgical planning and treatment of breast carcinoma. Evaluation of clinical pathways and patient outcomes for breast magnetic resonance imaging (MRI) in preoperative assessment and...</p> <p>Find out more</p>	<p>CALOR IBCSG 27-02/BIG 1-02/NSABP Trial B-37: CALOR</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>A randomised clinical trial of adjuvant chemotherapy for radically resected loco-regional relapse of breast cancer.</p> <p>Find out more</p>
<p>DIAMOND BCT 1703: DIAMOND</p> <p>Metastatic</p> <p>Open</p> <p>An investigator-initiated, non-randomised, phase II study of combination CTLA-4 and PD-L1 blockade in combination with HER2 blockade in advanced HER2-positive breast cancers that have progressed on prior trastuzumab-based therapy</p> <p>Find out more</p>	<p>DOMINO ANZ 1301: DOMINO</p> <p>Prevention</p> <p>Closed</p> <p>Neoadjuvant (pre-operative) systemic therapy is one of an increasing number of treatment options available for breast cancer. Patients may be asked to make complex decisions about the time when they are dealing with stress of...</p> <p>Find out more</p>	<p>ELIMINATE ANZ 1401: ELIMINATE</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>Treatment of breast cancer often involves surgery first which may be followed by additional treatment. However, neoadjuvant therapy (treatment before</p>	<p>Capecitabine ANZ 0001: Capecitabine</p> <p>Metastatic</p> <p>Closed</p> <p>A phase III trial to evaluate oral chemotherapy with Capecitabine versus standard chemotherapy with CMF in</p>	<p>CAPTURE BCT 1901: CAPTURE</p> <p>Metastatic</p> <p>Open</p> <p>Circulating tumour DNA Assessment of PIK3CA to guide Treatment Response (CAPTURE). A phase II randomised study to evaluate alpelisib plus fulvestrant versus capecitabine in oestrogen receptor positive, HER2-negative advanced breast cancer...</p> <p>Find out more</p>	<p>CASA IBCSG 32-05/BIG 1-05: CASA</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>Phase III Trial Evaluating the Role of Adjuvant Pegylated Liposomal Doxorubicin (PLD, Caelyx®, Doxil®) for Women (age 66 years or older) with Endocrine Nonresponsive Breast Cancer Who Are NOT Suitable for Being Offered a "Standard Chemotherapy..."</p> <p>Find out more</p>
	<p>ALTT0 ANZ 0702/BIG 2-06/N063D/EGF106708: ALTT0</p> <p>Early Breast Cancer</p> <p>Closed</p> <p>A randomised, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer.</p> <p>Find out more</p>	<p>ANZ 0601 ANZ 0601/CIRG/TORI 010</p> <p>Metastatic</p> <p>Closed</p> <p>A randomised phase II trial of double-blind, placebo controlled AMG 706 in combination with paclitaxel, or open-label bevacizumab in combination with paclitaxel, as first line therapy in women with HER2-negative locally recurrent or metastatic...</p> <p>Find out more</p>	<p>ANZ 7801 ANZ 7801</p> <p>Metastatic</p> <p>Closed</p> <p>Phase III randomised trial to compare endocrine treatment (oophorectomy) versus cytotoxic chemotherapy (adriamycin plus cyclophosphamide) versus oophorectomy plus cytotoxic chemotherapy in premenopausal patients with advanced breast cancer.</p> <p>Find out more</p>		
	<p>ANZ 7802 ANZ 7802</p> <p>Metastatic</p> <p>Closed</p> <p>Phase III trial to evaluate hormone therapy (tamoxifen) versus cytotoxic chemotherapy (adriamycin plus cyclophosphamide) versus hormone therapy plus cytotoxic chemotherapy as first line therapy in postmenopausal patients with advanced breast cancer.</p> <p>Find out more</p>	<p>ANZ 8101 ANZ 8101</p> <p>Metastatic</p> <p>Closed</p> <p>Phase III trial to evaluate continuous versus intermittent combination chemotherapy in advanced breast cancer.</p> <p>Find out more</p>	<p>ANZ 8102 ANZ 8102</p> <p>Metastatic</p> <p>Closed</p> <p>Phase III trial to evaluate optimal endocrine treatment with oophorectomy and tamoxifen in premenopausal patients with advanced breast cancer.</p> <p>Find out more</p>		

Why consider a Clinical Trial

- You may get access to a new type of treatment.
- You will get an excellent standard of care and be closely monitored by doctors, research nurses and other health professionals.
- Research shows that patients treated in clinical trials usually fare better than those who are not involved.
- You will be helping researchers develop new treatments for breast cancer that will help others in the future.

Some types of Clinical Trials

- Prevention trials – the switch from 5 to 10 years of endocrine therapy for hormone positive early BC
- Screening trials – CAPTURE
- Treatment trials – breast conserving surgery followed by RT can have similar outcomes to mastectomy for early BC

STARs outcomes for women given hormone therapy before or after radiotherapy 10 year follow up

- Supportive care trials – unmet needs

there are many others.....

Considerations in a Treatment Clinical Trial

- The new treatment may not be better than or as good as standard treatment
- You may receive the standard of care treatment not the trial treatment or even a placebo
- New treatments may have unexpected side effects or worse than those from standard treatment
- You may need to make more visits to the doctor and be required to undergo extra investigations than if you were on standard treatment
- A new treatment may benefit some patients but not all
- Access to a clinical trial might involve travel interstate with added expenses and separation from support network

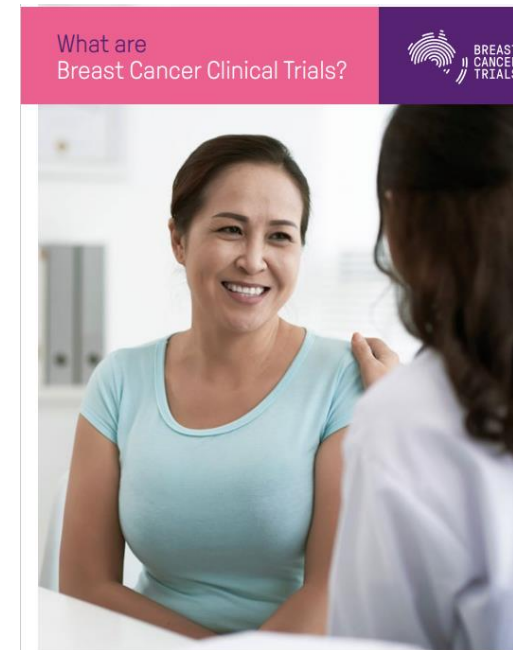
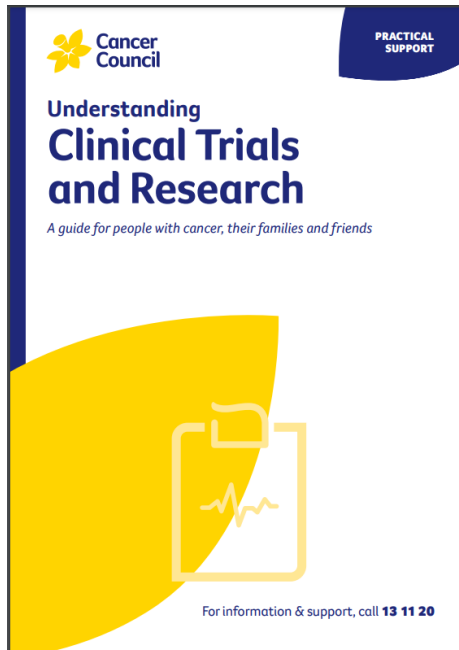
Questions to you might ask

- ❖ What is the aim of the clinical trial?
- ❖ Who is running the clinical trial?
- ❖ What are the possible benefits and risks of taking part in the clinical trial?
- ❖ Why am I eligible to take part in this trial?
- ❖ How long will I participate in the clinical trial?
- ❖ Why do the researchers think this treatment will work for my cancer?
- ❖ What is known about the drug/s being used in this trial?
- ❖ How is it decided which treatment I will receive? Will I know? Will my doctor know?
- ❖ How often will I have to attend appointments as part of the trial?
- ❖ Who will be part of my clinical trial team?
- ❖ If I gain benefit from this trial, will I be able to keep receiving the treatment after the trial ends?
- ❖ When will I know the results of the clinical trial?

Some barriers to participating in clinical trials

- Regional & rural location
- Culturally and linguistically diverse, including indigenous
- Other health conditions
- Male breast cancer
- Lack of information

Resources

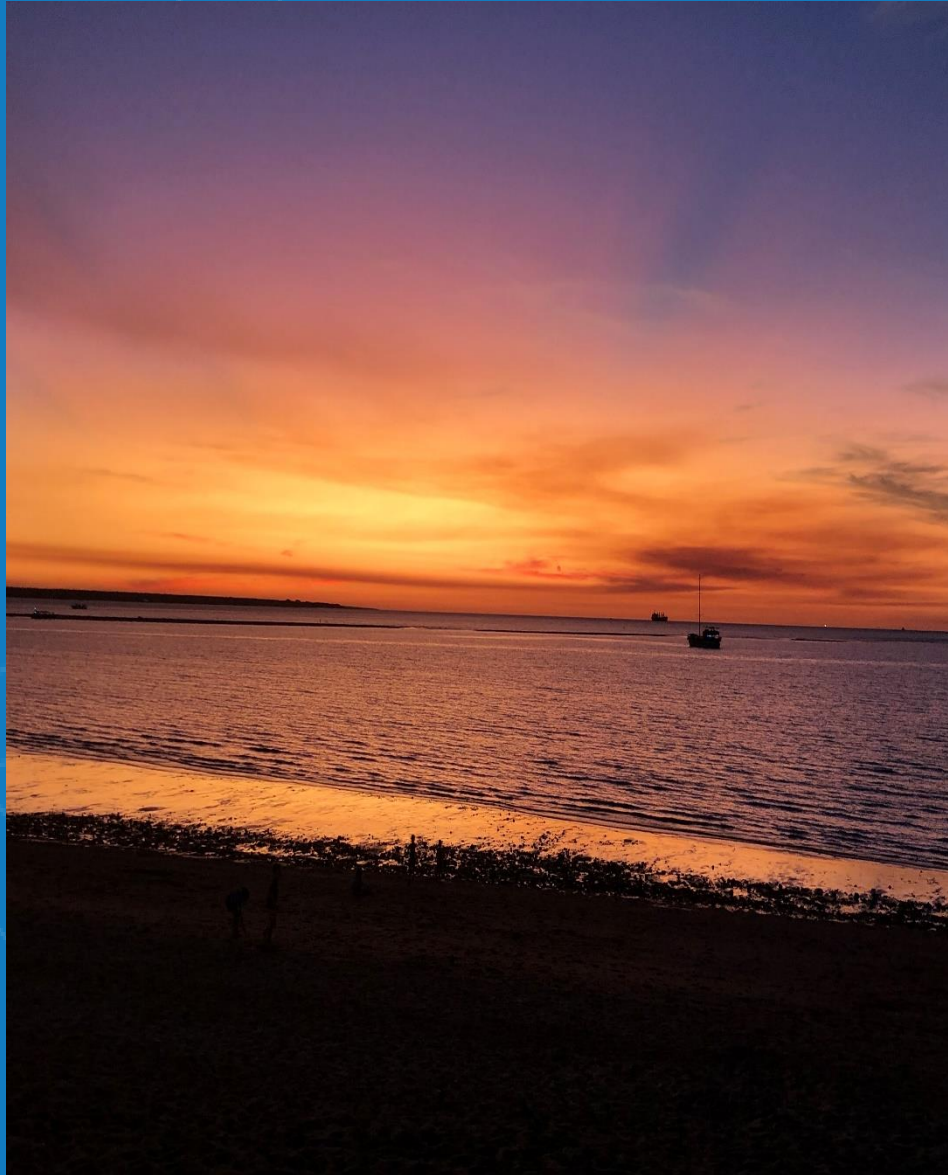


Resources

- <https://www.cancercouncil.com.au/wp-content/uploads/2022/01/Understanding-Clinical-Trials-and-Research-2022.pdf>
- <https://www.breastcancertrials.org.au/wp-content/uploads/2021/11/What-Are-BCCT.pdf>
- https://www.bcna.org.au/media/7426/bcna_clinicaltrials_factsheet_mar19.pdf

Herceptin – HERA trial





"improving the quality of life of breast cancer patients and helping them to live longer is always at the front of our minds when we conduct our research"

*Associate Professor Shom Goel
Peter MacCallum Cancer Centre*

Thank you