

First-in-Dog (FiDo) Cure Cancer Initiative

Clinical trial opening for dogs with mammary cancer in 2023



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A new trial initiative by the [School of Animal & Veterinary Sciences](#) and the [Dame Roma Mitchell Cancer Research Laboratories](#)

Mammary (breast) cancers arise spontaneously in female dogs, and these are like human breast cancers in many ways. Like breast cancers in women, many canine mammary tumours are driven by the hormone estrogen. Drugs that target the estrogen receptor (ER) are prescribed for treatment of breast cancer in women, but these drugs have toxic side-effects in dogs. Hence, surgery remains standard-of-care for canine mammary cancer. However, surgery can be debilitating for a dog, is expensive, and does not eliminate cancer cells that have spread to other organs, which can ultimately result in death.

The proposed trial investigates an exciting new medical therapy for dogs based on a ground-breaking study from the University of Adelaide showing that drugs activating the androgen receptor (AR) are an effective, durable, and well tolerated treatment strategy for ER-driven breast cancer. In humans, AR activation drugs also have positive effects on bone, muscle, and mental clarity. Our aim is to develop a safe medical treatment for mammary cancer in dogs that is affordable, improves quality of life and is also effective in treating metastatic cancers that have spread to other organs. Importantly, this study will not only benefit dogs with mammary cancer but will also inform how best to use this treatment for women with breast cancer.

The University of Adelaide Team

The team comprises researchers and animal care staff with expertise in oncology, surgery, translational research, pathology and clinical trials. It is co-led by **Prof Wayne Tilley**, a pioneer of sex hormone receptor action in breast and prostate cancers and Director of the Dame Roma Mitchell Cancer Research Laboratories (DRMCRL), and **Assoc. Prof Anne Peaston**, a veterinary oncologist and clinical lead at the Roseworthy Veterinary Hospital (formerly the Companion Animal Health Centre), Roseworthy.



What is involved for your dog?

There are 3 phases of the FiDo study. Discuss with your vet the possibility of participating as follows:

Phase 1: Simple donation of fresh mammary tissue removed during surgery will help to analyse ER and AR action, including testing medical therapies using a unique method developed by the research team.

Phase 2: Window of Opportunity Study – 2 weeks before surgery:

A short study to determine whether there is a response to an AR activation drug. Your dog will be randomly assigned to one of 3 treatment arms: AR activation treatment (T + Ai) through an implant under the skin; ER target treatment used in women (Anastrozole; Ai) with a daily oral tablet; or a placebo treatment. A tumour biopsy will be collected at the start and end of the 2 weeks to assess treatment response. Surgical biopsy costs are subsidised, as are any additional procedures outside standard-of-care.

Phase 3: Option to continue – up to 12 months:

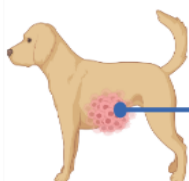
A longer term study following surgery to examine the treatment effects on quality-of-life, delay of tumour recurrence and prevention of cancer metastasis. Your dog will be randomly assigned to 1 of 2 treatment arms: AR activation treatment (T + Ai) or standard-of-care treatment. Over the next year, your dog will have monthly check-ups, up to three CT scans under anaesthesia, and re-insertion of a new AR activation implant every 3 months under anaesthesia. If drug resistance or cancer progression occurs after surgery, your dog will go off the study and other therapy can be considered with your veterinarian's input.

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Please add in Subject line: dog mammary cancer

Canine mammary cancer



The current approach:



- Cannot treat metastases
- Expensive
- Side-effects/long recovery
- Quality of life compromised

A new medical therapy:



- Implanted under skin
- Block tumour growth
- Increased survival
- Prevent/treat metastasis
- Improved wellbeing