



Anastrozole for women with chemotherapy-resistant advanced hormone-positive ovarian cancer

Paragon (also known as ANZGOG 0903) is a group of 7 trials involving women with potentially hormone-responsive cancers of the uterus and ovaries. The trials are helping researchers answer some important questions about the role of anti-estrogens to treat these cancers. The results could change the way some cancers are treated in the future and lead to new research questions as well.

We acknowledge and appreciate the important part played by our volunteer participants who enrolled in Paragon. Here is a summary of one of the trials. The other trials are still being analysed.

What was the trial about?

The 7 Paragon trials have recruited 338 women in Australia, UK, New Zealand and Belgium.

The trial described here included 53 participants from Australia and New Zealand. They all had advanced-stage recurrent ovarian cancer that had become resistant to chemotherapy.

Women were eligible for the trial if their tumours were hormone-receptor positive on tissue staining and were therefore more likely to respond to an anti-estrogen drug.

The drug used was anastrozole (trade name Arimidex), which is an aromatase inhibitor. It reduces the amount of estrogen produced in the body in women who are past menopause.

The trial aimed to test whether anastrozole would stop or reverse the growth of the tumour. It was known from earlier studies that on chemotherapy or no treatment, most of these cancers would become worse after a few weeks. Therefore, the effect of anastrozole after 12 weeks was analysed, although participants continued on treatment as long as it benefited them.

The women all received the study treatment—a 1 mg tablet daily. There was no control group. They were aged 65 years on average. Nearly half of them had already undergone at least 3 different courses of chemotherapy.

How was the effect of treatment measured?

Tumours were measured by CT scan, and the change in size since starting the trial was analysed. A cancer marker in the blood, CA125, was also measured each month.

The researchers also measured progression-free survival—that is, the time between the participant's entry into the trial until the disease became worse.

Any toxic effects of treatment were recorded. The participants reported on their quality of life and on any medical problems.

Was the new treatment effective?

The treatment affected the women in different ways. Some did better than others. The treatment did not reduce the size of any tumours, but for 13 patients, their cancer did not grow.

The cancer marker, CA125, improved for 3 women. 18 showed a clinical benefit; that is, their CA125 level improved or remained stable.

The patients who had clinical benefit based on no change in their scans or CA125 level also had better quality-of-life scores.

12 women were able to continue on anastrozole for 4 months, and 7 continued on it for more than 6 months.

What were the side-effects of the treatment?

Anastrozole treatment was generally well tolerated. Half of the patients suffered from fatigue. This may have been related to their cancer.

The most common side-effects were hot flushes (43%), joint pain (39%), nausea (24%) and loss of appetite (24%). These were usually mild.

8 women stopped treatment early, mainly because their disease became worse, including 2 patients who stopped because of side effects.

Were there any side-effects causing hospital admission?

No serious side-effects of the treatment were reported. Some women had medical problems related to their cancer that required admission to hospital.

What does this mean for trial patients?

The trial was small and the patients were very variable in how their cancers responded to the treatment. On average, the hormone treatment had a clinical benefit for longer and with fewer side-effects than would be expected with chemotherapy.

How will the results help patients and doctors in future?

This trial has provided new information on the effects of hormone therapy for a particular type of ovarian cancer. A small group of women do benefit from anti-estrogen therapy. The challenge is to identify who these patients are.

The approach of doing 7 trials in one (also known as a basket protocol) is a new way of running clinical trials for patients with uncommon tumours. It means that various kinds of cancers can be included in the one trial protocol. This suits rare cancers. The experience of Paragon will help investigators undertaking trials the future.

What will the researchers do next?

The researchers concluded that it will be worthwhile to continue to investigate hormone therapies like anastrozole for women with ovarian cancer resistant to chemotherapy. The aim would be to narrow down which patients are most likely to benefit.

Where can I find out more about the trial?

Talk with your GP or oncologist.

The results have been published in a scientific journal

Bonaventura A, and others. Paragon (ANZGOG-0903): phase 2 study of anastrozole in women with estrogen or progesterone receptor-positive platinum-resistant or -refractory recurrent ovarian cancer. *International Journal of Gynecological Cancer* 2017; volume 27, issue 5: pages 900–906. [Summary](#)

Trial registration

Australian New Zealand Clinical Trials Registry
www.anzctr.org.au
registration number [12610000796088](https://www.anzctr.org.au/Trial/Registration/Trial.jsp?id=12610000796088)

Australia New Zealand Gynaecological Oncology Group

[Link](#) to website and summary of the trial

The sponsor of this part of Paragon was the Australia New Zealand Gynaecological Oncology Group (ANZGOG). The trial was funded by Cancer Australia (grant 632740 and Priority-Driven Collaborative Cancer Research Scheme 1063014). AstraZeneca provided anastrozole.

The authors of the journal article reporting the results declared no conflicts of interest.

Results of any clinical trial do not represent complete knowledge about treatment. Patients should not change their therapy on their understanding of the results.