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ACT 4 PLATO

PersonaLising Anal cancer radioTherapy dOse

Participant Early Results Summary

Standard versus dose reduced chemoradiotherapy in anal cancer

We are indebted to all patients who took part in the ACT4 trial and thank you for your participation past, present and possibly in the future. We also thank all the members of the medical teams and research staff who looked after and delivered the treatment and cared for those patients taking part in the trial.

This summary will provide you with details on the early results of the trial.

What is the purpose of the trial?

Previous research has shown that early anal cancers are best treated with a combination of chemotherapy (anti-cancer drugs) and radiotherapy (high energy X-rays). We have been exploring the option of giving less radiotherapy than is usually given to patients with early anal cancer as standard treatment. An early cancer is one that is relatively small and has not spread anywhere else. Further details on the background of the trial can be found on the CRUK website here or in the Patient Information Sheet provided at the start of the trial.

The side effects that occur during chemoradiotherapy and for a few weeks after finishing treatment are known as '**acute' side effects**. They usually get worse towards the end of treatment and then gradually get better a few weeks after treatment has ended but may take some months to settle.

The trial has now closed to recruitment and patients are in the follow up stage. We can share the early results of how the cancers responded to treatment and the acute side effects for both groups. We need to wait longer before we can analyse the final results, which will look at the ability of both treatments to cure the cancer and at the longer term "chronic" side effects, which may only start many months after treatment has finished.

We had indicated to all the trial participants that we would prepare a summary of the results. This summary is being made available to patients at the same time as the

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results are being presented at an international cancer conference for oncologists in Vienna in May 2023.

What are the results of the trial so far?

From April 2017 to December 2020 the ACT4 trial recruited 160 patients from cancer centres across the UK whose information has been used in this early analysis. 55 patients received the standard treatment over 5½ weeks and 105 patients received the experimental treatment over 4½ weeks.

Three quarters of the patients were women: anal cancer is known to be more common in women. The average age of patients was 64 with the youngest being 35 and the oldest being 87.

Six months after radiotherapy, 83.6% of patients in the standard 5½ week group and 84.8% in the experimental 4½ week group had no evidence of anal cancer

45.5% of patients in the standard treatment group and 35.2% of patients in the experimental treatment group had severe 'acute' side effects.

Patients were asked to complete quality of life questionnaires at regular intervals during and after their treatment. At six months, it was found that there is no marked difference in quality of life between the two groups but there is a suggestion of fewer side effects regarding sexual function in female and male participants treated with the lower dose.

What did the results show?

These early results show that both the standard and experimental (shorter) treatments are very similar in terms of eradication of anal cancer. Severe early side effects from the treatments were more common in patients with the standard (longer) treatment but this was not evident in the questionnaires completed by patient up to 6 months from their treatment.

What will happen now?

Although we have performed this analysis, the trial has not finished and participants are still being followed up.

The final results of the ACT4 study will be ready for analysis in late 2024 and we will be back in touch then.

Funding

We are grateful for the support the ACT4 trial received from Cancer Research UK and Stand up to Cancer