Participant Early Results Summary

Standard versus dose increased chemoradiotherapy in anal cancer

We are indebted to all patients who took part in the ACT5 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 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 more radiotherapy than is usually given to patients with more advanced anal cancer. A more advanced anal cancer is one that is a little larger and/or may have spread to local lymph nodes. In this study, patients are randomised to receive the standard dose of radiotherapy or may receive one of two different, slightly higher doses of radiotherapy. 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.

Recruitment to this trial is still ongoing but we planned to look at the early side effects of the different treatments after the first 140 patients treated. This summary provides the results of the first 140 patients only.

Recruitment is likely to close in Summer 2023 when we have recruited 459 participants in total. Currently we have recruited 440 participants and we will update with the results of the wider group at a later date.

We can share the early results of patient side effects up to 3 months after finishing treatment for the first 140 patients treated. We need to wait longer before we can analyse the full results, which will look at the ability of the three different 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. The results were also presented at an international cancer conference for oncologists in Copenhagen in May 2022.

What are the results of the trial so far?
Between February 2017 and April 2020, 140 patients were recruited from 37 UK sites.47 patients received the standard treatment over 5½ weeks. 47 and 46 patients respectively, received two different experimental treatments, receiving higher radiotherapy doses to their tumour and lymph nodes over 5½ weeks.

Just over three quarters of the patients were women: anal cancer is known to be more common in women. The average age of patients was 60 with the youngest being 36 and the oldest being 77. There were no significant delays to radiotherapy treatment and changes to chemotherapy (such as missing or reducing doses) were similar in all groups.

49% of patients in the standard treatment group, and 52% and 44% respectively of patients in the two different experimental treatment groups had severe 'acute' side effects during treatment. At 6 weeks following treatment, side effects were a little higher (17% and 13%) in the higher dose groups compared to the standard treatment group (3%). However, these had settled to <5% severe side effects in all groups by 3 months after treatment.

Patients were asked to complete quality of life questionnaires at regular intervals during and after their treatment. Patients reported that their side effects and quality of life were worst in the last week of treatment with no differences between the different treatments. By 6 weeks, it was found that there was no marked difference in quality of life between the three groups and no differences found between the three different treatments in terms of pain and bowel symptoms at this early stage.

What did the results show?
These early results show that both the standard and experimental (higher dose) treatments are very similar in terms of early side effects of treatment.

What will happen now?
Although we have performed this analysis, the trial has not finished, and participants are still being recruited and all participants will continue to be followed up.

The final results of the ACT5 study will be ready for analysis in late 2026 and we will be back in touch then.

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