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ACT 3

PLATO

PersonaLising Anal cancer radioTherapy dOse

Participant Early Results Summary

Strategy for treating patients with early cancer of the anus after removal by local excision surgery with selective use of reduced dose postoperative chemoradiotherapy

We are indebted to all participants who took part in the ACT3 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 participants 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?

Prior to ACT3 there was no agreement on how we should treat patients with early anal cancer. The purpose of ACT3 was to establish a treatment for early anal cancer. We wanted to ensure the proposed treatment was acceptable in terms of the chance of remaining cancer free at 3 years after the treatment (3 year loco-regional failure free rate), the side effects of treatment and quality of life of the participants treated. 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.

All participants had early anal cancer that had been surgically removed with a small excision and no further treatment. If the cancer was entirely removed, participants went on to close monitoring. If there was a too small (close) margin between the cut edge of the specimen and the tumour, participants went on to receive 4.5 weeks of chemoradiotherapy (<1mm). Chemoradiotherapy is a combination of chemotherapy (anti-cancer drugs) and radiotherapy (high energy X-rays).

What are the results of the trial so far?

Between March 2017 and August 2023 the ACT3 trial recruited 83 participants from cancer centres across the UK. Of the 83 participants in the trial, 71% were women and 29% men. The average age was around 56-61 years of age. 39 participants had all the cancer removed at excision and went on to close monitoring. 44 participants went

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on to receive chemoradiotherapy. Of those receiving chemoradiotherapy, all participants finished the radiotherapy as planned and on time. Twenty-seven of these participants had no changes made to their chemotherapy, and only 7 participants needed a change to chemotherapy due to side effects. Four participants had a serious side effect of chemotherapy; two were heart related, one was gastrointestinal and one was inflammation of the skin due to radiation treatment.

In terms of quality of life, in the group that received chemoradiotherapy, general quality of life issues, tiredness, pain and bowel symptoms were worse towards the end of treatment but improved back to pre-treatment levels by 6 months.

What did the results show?

These early results suggest that while there are short term side effects, these are short lived and at 6 months the quality of life in both groups appeared broadly similar. In the group that were treated by observation alone, there were broadly no changes in quality of life throughout the first 6 months of the trial.

What will happen now?

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

We look forward to the longer-term outcomes of the trial, which will include the number of participants who remain cancer free at 3 years and the quality of life over that timeframe. Further information will be made available for participants in 2027 when this data is reported.

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