The SOPRANO Trial: Stereotactic Radiotherapy Alone or Followed by Niraparib for Oligometastases or Oligoprogression in Ovarian Cancer following PARP Inhibitor Therapy

Lay Summary

Introduction to SOPRANO

SOPRANO is a phase II clinical trial to assess whether a type of radiotherapy called **stereotactic body radiotherapy (SBRT)** which targets radiotherapy very precisely at cancer cells, either on its own or followed by **niraparib**, a type of drug called a PARP inhibitor (PARPi), increases the length of time before patients with some forms of advanced ovarian cancer need to start a different treatment such as chemotherapy.
For the purposes of the SOPRANO trial:

- The term 'ovarian cancer' includes ovarian, fallopian tube and primary peritoneal cancer.
- Oligoprogression refers to cancer which has either gotten bigger and/or spread to a small number of places (1-3) in the body.
- Oligometastases refers to cancer which has spread to a small number of places (1-3) in the body.

Patients will be randomly allocated to receive either SBRT followed by Niraparib (group 1) or SBRT alone (group 2). 21 patients will be allocated to each treatment group.

Stereotactic Body Radiotherapy (SBRT)

Radiotherapy involves the use of targeted beams of high energy X-rays to kill cancer cells. Radiotherapy cannot tell the difference between cancer cells and normal cells and the radiotherapy team carefully plans the treatment so that only the cancer and as few normal cells as possible receive the highest dose of radiotherapy. SBRT is a way of targeting radiotherapy very precisely to the cancer using lots of beams at different angles to ensure that a very high radiation dose is given to the cancer and as low a dose as possible is given to surrounding healthy tissues.

Niraparib

Niraparib is the name of the treatment being investigated in the SOPRANO clinical trial. It is a type of targeted therapy called a PARP inhibitor (PARPi). PARPs are proteins that help damaged cells repair themselves. Niraparib blocks (inhibits) how PARP proteins work in cancer cells. Without PARP proteins, these cancer cells become too damaged to survive and they die. We want to see whether the use of this drug can increase the amount of time a patient benefits from SBRT. Niraparib is currently approved for use as a maintenance treatment for patients with early or relapsed ovarian, fallopian tube or primary peritoneal cancer who have completed chemotherapy treatment and achieved a good response.

Trial Treatment

In both treatment groups, participants will receive between 3 and 8 doses of SBRT spread over 5 to 19 days. Participants in treatment group 1 will then receive Niraparib once a day until their disease worsens. All participants will attend follow up visits for clinical and imaging assessments every 8 weeks during the first year, reducing to every 12 weeks in the second year and then as deemed necessary by their local hospital team. Participants whose disease worsens but remains within 1-3 places of progression or metastases may be considered for further SBRT treatment.

Purpose of Trial

Data collected from both treatment groups will be analysed at the end of the trial to determine whether the use of SBRT with or without niraparib increases the number of patients whose cancer has not progressed at 6 months after starting treatment. If the number of patients whose cancer has not progressed is greater than a number agreed by the investigators when setting up the trial, further trials involving this treatment will be considered. The results will be shared with all participants and published publicly to inform future research with the aim of making a difference to future cancer patients.