



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.

Participants will have a discussion with their clinician and choose one of two treatment options:

- SBRT followed by niraparib (group 1)
- SBRT on its own (group 2)

Up to 21 patients will join 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 participant

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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

Participants in both groups will receive between 3 and 8 doses of stereotactic body radiotherapy (SBRT) over a period of 5 to 19 days.

Participants in treatment group 1 will then receive niraparib once a day. This will continue for as long as it is helping and until the cancer gets worse.

All participants will attend regular follow-up visits. These will include check-ups and scans to monitor their health and how the treatment is working:

- Every 8 weeks during the first year
- Every 12 weeks during the second year
- After this, timing will be decided by their hospital team

If the cancer worsens but is still limited to 1–3 areas, participants may be offered further SBRT treatment, depending on their individual situation.

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 the 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.